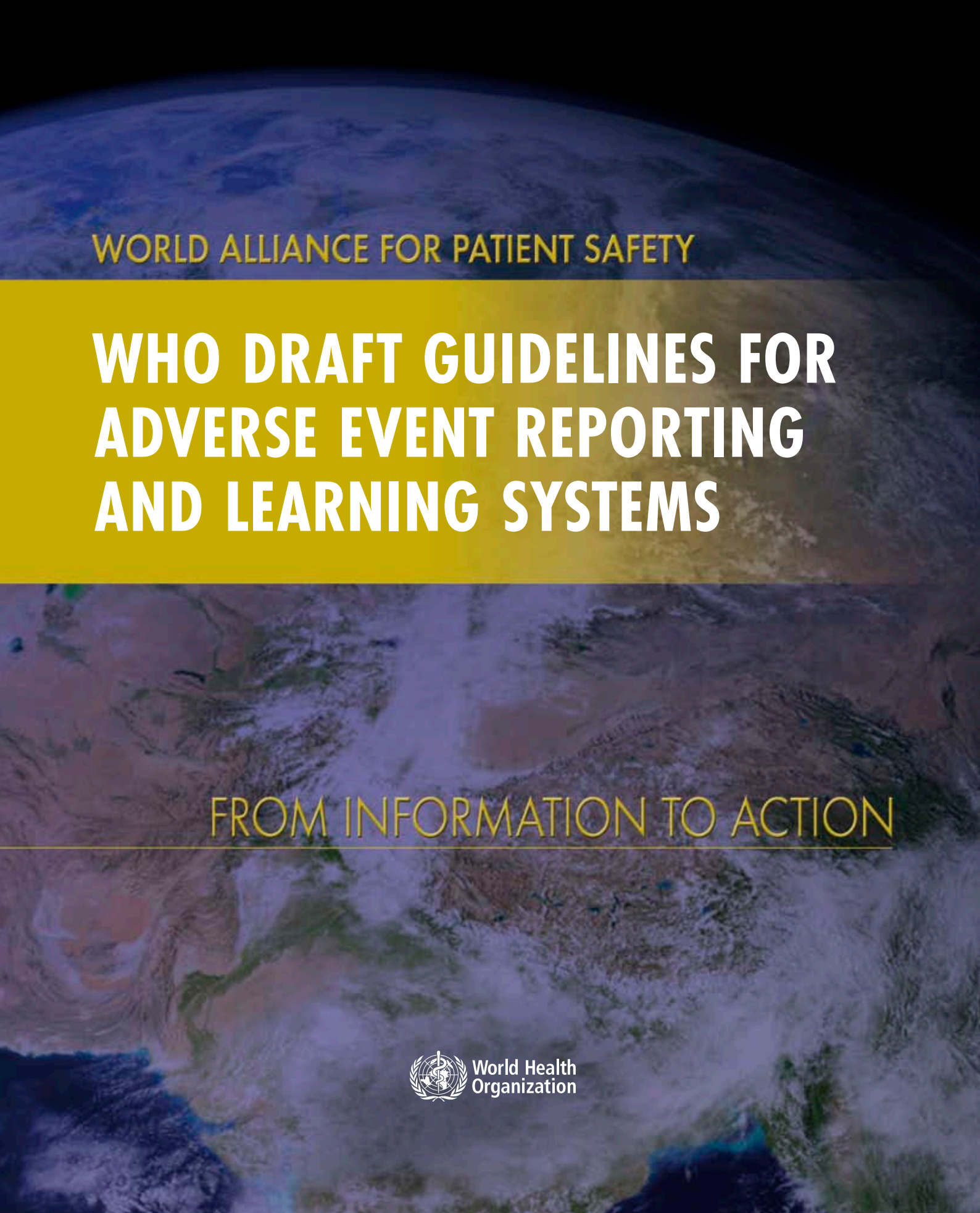
WORLD ALLIANCE FOR PATIENT SAFETY
WHO DRAFT GUIDELINES FOR ADVERSE EVENT REPORTING AND LEARNING SYSTEMS
FROM INFORMATION TO ACTION
World Health Organization

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FOREWORD

Imagine a jet aircraft which contains an orange coloured wire essential for its safe functioning. An airline engineer in one part of the world doing a pre-flight inspection spots that the wire is frayed in a way that suggests a critical fault rather than routine wear and tear. What would happen next? I think we know the answer. It is likely that – probably within days – most similar jet engines in the world would be inspected and the orange wire, if faulty, would be renewed.

When will health-care pass the orange-wire test?

The belief that one day it may be possible for the bad experience suffered by a patient in one part of the world to be a source of transmitted learning that benefits future patients in many countries is a powerful element of the vision behind the WHO World Alliance for Patient Safety.

The most important knowledge in the field of patient safety is how to prevent harm to patients during treatment and care. The fundamental role of patient safety reporting systems is to enhance patient safety by learning from failures of the health care system. We know that most problems are not just a series of random, unconnected one-off events. We know that health-care errors are provoked by weak systems and often have common root causes which can be generalized and corrected. Although each event is unique, there are likely to be similarities and patterns in sources of risk which may otherwise go unnoticed if incidents are not reported and analysed.

These draft guidelines are a contribution to the Forward Programme 2005 of the World Alliance for Patient Safety. The guidelines introduce patient safety reporting with a view to helping countries develop or improve reporting and learning systems in order to improve the safety of patient care. Ultimately, it is the action we take in response to reporting – not reporting itself – that leads to change.

Reporting is fundamental to detecting patient safety problems. However, on its own it can never give a complete picture of all sources of risk and patient harm. The guidelines also suggest other sources of patient safety information that can be used both by health services and nationally.

The currency of patient safety can only be measured in terms of harm prevented and lives saved. It is the vision of the World Alliance that effective patient safety reporting systems will help to make this a reality for future patients worldwide.

Sir Liam Donaldson

Chair
World Alliance for Patient Safety

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1. INTRODUCTION

Reducing medical errors has become an international concern. Population-based studies from a number of nations around the world have consistently demonstrated unacceptably high rates of medical injury and preventable deaths. In response, a global effort, the World Alliance for Patient Safety, has been launched by WHO to galvanize and facilitate efforts by all Member States to make health care safer.

These draft guidelines are a contribution to the Forward Programme 2005 of the World Alliance for Patient Safety (1). The guidelines introduce adverse event reporting and focus on reporting and learning to improve the safety of patient care.

Purposes of reporting

In seeking to improve safety, one of the most frustrating aspects for patients and professionals alike is the apparent failure of health-care systems to learn from their mistakes. Too often neither health-care providers nor health-care organizations advise others when a mishap occurs, nor do they share what they have learned when an investigation has been carried out. As a consequence, the same mistakes occur repeatedly in many settings and patients continue to be harmed by preventable errors.

One solution to this problem is reporting: by the doctor, nurse, or other provider within the hospital or health-care organization, and by the organization to a broader audience through a system-wide, regional, or national reporting system. Some believe that an effective reporting system is the cornerstone of safe practice and, within a hospital or other health-care organization, a measure of progress towards achieving a safety culture. At a minimum, reporting can help identify hazards and risks, and provide information as to where the system is breaking down. This can help target improvement efforts and systems changes to reduce the likelihood of injury to future patients.

Objectives

The objective of these draft guidelines is to facilitate the improvement or development of reporting systems that receive information that can be used to improve patient safety. The target audience is countries, which may select, adapt or otherwise modify the recommendations to enhance reporting in their specific environments and for their specific purposes. The guidelines are not meant to be an international regulation and will undergo modification over time as experience accumulates.

The guidelines draw on a review of the literature about reporting systems, a survey of countries about existing national reporting systems, and the experience of the authors.

Reporting may capture errors, injuries, non-harmful errors, equipment malfunctions, process failures or other hazards (see definitions below). While an individual report may contain important information about a specific incident or event, the notion of a reporting system refers to the processes and technology involved in the standardization, formatting, communication, feedback, analysis, learning, response, and dissemination of lessons learned from reported events.

Reports are generally initiated by health-care workers such as care providers or administrators from hospitals, ambulatory sites, or communities. Reporting systems may also be designed to receive reports from patients, families, or consumer advocates.

Definitions

Safety: Freedom from accidental injuries (2).

Error: The failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning) (3). Errors may be errors of commission or omission, and usually reflect deficiencies in the systems of care.

Adverse event: An injury related to medical management, in contrast to complications of disease (4). Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable.

Preventable adverse event: An adverse event caused by an error or other type of systems or equipment failure (5).

"Near-miss" or "close call": Serious error or mishap that has the potential to cause an adverse event but fails to do so because of chance or because it is intercepted. Also called potential adverse event.

Adverse drug event: A medication-related adverse event.

Hazard: Any threat to safety, e.g. unsafe practices, conduct, equipment, labels, names.

System: A set of interdependent elements (people, processes, equipment) that interact to achieve a common aim.

Other commonly used terms:

Event: Any deviation from usual medical care that causes an injury to the patient or poses a risk of harm. Includes errors, preventable adverse events, and hazards (see also incident).

Incident (or adverse incident): Any deviation from usual medical care that causes an injury to the patient or poses a risk of harm. Includes errors, preventable adverse events, and hazards.

Potential adverse event: A serious error or mishap that has the potential to cause an adverse event but fails to do so because of chance or because it is intercepted (also called "near miss" or "close call") (6).

Latent error (or latent failure): A defect in the design, organization, training or maintenance in a system that leads to operator errors and whose effects are typically delayed (3).

Many other terms have been used: adverse outcomes, mishaps, untoward or unanticipated events, etc. WHO has commissioned the development of an international taxonomy for patient safety in order to promote greater standardization of terminology and classification. Meanwhile, for these guidelines we will use the simpler terms: errors, hazards, adverse events and incidents.

Why should individuals or health-care organizations report adverse events and errors?

Health-care organizations or individuals benefit from reporting incidents if they receive back useful information gained by generalizing and analysing similar cases from other institutions. Consider the following case: In an intensive care unit at a hospital, the oxygen tubing is inadvertently connected to an intravenous line and causes an air embolism. Investigation reveals that the tubing connectors are similar, the oxygen tubing had been left disconnected from a prior respiratory treatment, and the lights in the unit were dim. The hospital's response might include implementing a new policy requiring that all tubing be labelled, a weak and cumbersome solution.

If the event and the results of the analysis are not reported to an external authority, the lessons learned are trapped within the walls of that hospital. The opportunity to generalize the problem is lost and the opportunity to develop more powerful and generalizable solutions is missed.

In contrast, if the event is reported and the findings from the investigation are entered into a database, the event can be aggregated with similar incidents to elucidate common underlying causes. A variety of solutions could emerge, ranging from

nursing practice standards to label and trace all tubing, to a requirement for medical device manufacturers to develop incompatible connectors for all medical tubing.

Appendix 1 contains an excerpt from the landmark Institute of Medicine report To Err is Human, which provides an overview of the systems approach to human error within health-care and other industries.

Core concepts

The four core principles underlying the guidelines are:

- The fundamental role of patient safety reporting systems is to enhance patient safety by learning from failures of the health-care system.
- Reporting must be safe. Individuals who report incidents must not be punished or suffer other ill-effects from reporting.
- Reporting is only of value if it leads to a constructive response. At a minimum, this entails feedback of findings from data analysis. Ideally, it also includes recommendations for changes in processes and systems of health care.
- Meaningful analysis, learning, and dissemination of lessons learned requires expertise and other human and financial resources. The agency that receives reports must be capable of disseminating information, making recommendations for changes, and informing the development of solutions.

Organization of the Guidelines

Section 2 describes the role of reporting in enhancing patient safety, its purposes and the ways in which reporting can enhance safety.

Section 3 discusses the essential components of a patient safety reporting system, considering the types of systems, the process of reporting (what is reported, by whom, and how), analysis of reports, response and dissemination, and application of results.

Section 4 examines alternative sources of information for safety. Reporting is but one method of obtaining such information, not necessarily the best. Other sources of useful data are briefly described.

Section 5 provides information about several existing national reporting systems, both governmentally sponsored and those implemented by non-governmental agencies or groups. This illustrates the broad variation in how Member States have dealt with these issues.

Section 6 describes the characteristics of successful reporting systems. While experience is limited in health care, successful existing systems have common features in purpose, design and operation, that have general applicability.

Section 7 outlines the requirements for a national adverse event reporting system, including the mechanism for collecting reports, the capacity to perform investigations, the expertise required, the technical infrastructure, and the capacity to disseminate findings.

Section 8 concludes with recommendations to WHO Member States.

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2. THE ROLE OF REPORTING IN ENHANCING PATIENT SAFETY

Key messages

- **The primary purpose of patient safety reporting systems is to learn from experience.**
- **A reporting system must produce a visible, useful response to justify the resources expended and to stimulate reporting.**
- **The most important function of a reporting system is to use the results of data analysis and investigation to formulate and disseminate recommendations for systems change.**

The purpose of reporting adverse events and errors

The primary purpose of patient safety reporting systems is to learn from experience. It is important to note that reporting in itself does not improve safety. It is the response to reports that leads to change. Within a health-care institution, reporting of a serious event or serious "near-miss" should trigger an in-depth investigation to identify underlying systems failures and lead to efforts to redesign the systems to prevent recurrence.

In a state or national system, expert analyses of reports and dissemination of lessons learned are required if reports are to influence safety. Merely collecting data contributes little to patient safety advancement. Even monitoring for trends requires considerable expert analysis and oversight of the reported data.

The important point is that a reporting system must produce a visible, useful response by the receiver to justify the resources expended in reporting, or, for that matter, to stimulate individuals or institutions to report. The response system is more important than the reporting system.

Methods of learning from reporting

There are several ways in which reporting can lead to learning and improved safety. First, it can generate alerts regarding significant new hazards, for example, complications of a new drug. Second, lessons learned by health-care organizations from

investigating a serious event can be disseminated. Third, analysis of many reports by the receiving agency or others can reveal unrecognized trends and hazards requiring attention. Finally, analysis of multiple reports can lead to insights into underlying systems failures and generate recommendations for "best practices" for all to follow.

Alerts

Even a small number of reports can provide sufficient data to enable expert analysts to recognize a significant new hazard and generate an alert. An excellent example of this function is the series of warnings issued every two weeks by the Institute for Safe Medication Practices entitled "Medication Alert". This system was one of the first to call attention to the high risk of death following accidental injection of concentrated potassium chloride and recommend that this substance be removed from patient care units.

Investigation of serious events

In a health-care organization committed to safety, a serious (especially disabling or life-threatening) event will trigger an investigation to search for underlying causes and contributing factors. Ideally, every institution will respond to a serious event with an investigation. Alternatively, an external authority (such as the health ministry) can conduct an independent investigation. If the investigation is done well, systems analysis of a serious adverse event can yield significant insights into the vari-

ous contributing factors that lead to a mishap, and often suggest potential remedies. This information can then be disseminated to other organizations. Solutions to some common hazards, such as wrong site surgery, have been developed in response to lessons learned from investigations of serious incidents.

Analysis of large datasets

Detailed analysis of thousands of reports also makes it possible to identify hazards (1). In the Australian Incident Monitoring System (AIMS) classification system, information about an incident is entered into the database using the generic classification scheme of clinically relevant categories. Natural questions guide analysts through details of context and contributing causes to probe interrelationships among event types, risk factors, and contributing causes. Statistical correlations identify meaningful relationships and provide analyses that can generate insights into the overall systems of care.

In the United States, USP's MedMARx[SM] system receives thousands of reports of medication errors and adverse drug events confidentially from participating health-care organizations. These data are classified and fed back to health-care organizations with benchmarking from the entire database and with their own prior experience, to identify targets for improvement as well as providing monitoring of progress.

Systems analysis and development of recommendations

The most important function that a large reporting system can perform is to use the results of investigations and data analyses to formulate and disseminate recommendations for systems changes. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has performed this function using a relatively small number of thoroughly investigated incidents reported to its sentinel events monitoring programme. Similarly, in the United States, some of the state reporting systems have developed safety recommendations from their data.

An example of a system aimed at translating learning into safety improvements is the relatively new National Reporting and Learning System (NRLS) developed by the National Patient Safety Agency (NPSA) in England and Wales. Reports are aggregated and analysed with expert clinical input to understand the frequency of types of incidents, patterns, trends, and underlying contributory factors. The NPSA has a "solutions" programme, involving all stakeholders. Recent initiatives include reducing errors associated with infusion devices, changes in doses of methotrexate, and a hand hygiene campaign.

Accountability

Some reporting systems, such as those of state health departments in the United States have been developed primarily to hold health-care organizations accountable for ensuring safe practice. Accountability systems are based on the notion that the government has a fiduciary responsibility to ensure that health-care organizations take necessary precautions to ensure that care is safe (2). A serious and presumably preventable injury, such as amputation of the wrong leg, suggests that the hospital's error prevention mechanisms are defective (3). Knowing that there is oversight by a government agency helps maintain the public's trust.

Accountability reporting systems hold health-care organizations responsible by requiring that serious mishaps be reported and by providing disincentives (citations, penalties, sanctions) to continue unsafe practices (4). Reporting in these systems can also lead to learning, if lessons are widely shared (2). However, if the government agency does not have sufficient resources to investigate or to analyse reports and disseminate results, the opportunity for learning is lost. In addition, the risk of sanctions may make health-care organizations reluctant to report events that can be concealed.

Since most reports elicit no response, and lessons from investigations are seldom shared, health-care organizations often perceive reporting in these systems as all risk and no gain (5). The result is that typical accountability systems receive relatively few reports. This is unlikely to change unless more resources are provided for analysis and reporting, and the consequences of reporting are made less punitive.

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3. COMPONENTS OF A REPORTING SYSTEM

Key messages

- **Current reporting systems span a spectrum of objectives incorporating both learning and accountability considerations.**
- **The primary objectives of a reporting system will determine the design, for example, whether reporting is voluntary and confidential.**
- **Reporting systems need to be clear on who reports, the scope of what is reported and how reports are made.**
- **Reporting of incidents is of little value unless the data collected are analysed and recommendations are disseminated.**
- **Experts who understand statistical methods, the practice concerns, clinical significance, systems issues, and potential preventive measures are essential to analyse reported incidents.**
- **Classification and simple analytic schemes start the process of categorizing the data and developing solutions that can be generalized.**

Types of systems

Current reporting systems span a spectrum of specific aims. At one end of the spectrum are reporting systems that focus on learning and contributing to system redesign. At the other end are systems developed by external regulatory or legal agencies primarily to ensure public accountability. These latter systems typically seek to identify health-care organizations where the level of care is unacceptable, for corrective action or discipline.

In practice, reporting systems may seek to address multiple objectives. Striking a balance within a single system between the aims of public accountability and learning for improvement is possible, but most reporting systems focus on one or the other. Although these aims are not necessarily incompatible, the primary objectives of the system will determine several design features, including whether the reports

are mandatory or voluntary, and whether they are held in complete confidence, or reported to the public or to regulatory agencies.

Learning systems

Reporting to learning systems is usually voluntary, and typically spans a wider scope of reportable events than the defined set of events typically required by a mandatory system. Rather than assure a minimum standard of care, learning systems are designed to foster continuous improvements in care delivery by identifying themes, reducing variation, facilitating the sharing of best practices, and stimulating system-wide improvements. Following careful expert analysis of underlying causes, recommendations are made for system redesign to improve performance and reduce errors and injuries.

In Australia, for example, over 200 health-care organizations or health services voluntarily send incident reports to the Australian Incident Monitoring System (AIMS) sponsored by the Australia Patient Safety Foundation (APSF). AIMS uses the Healthcare Incident Types (HIT) classification system, which elicits very detailed information from the reporter regarding generic incident types, contributing factors, outcomes, actions, and consequences.

The Japan Council for Quality Health Care collects voluntarily reported adverse events from health-care organizations in Japan, particularly sentinel cases with root cause analysis. A research team led by Tokai University asks health-care organizations to voluntarily pool their events, which are then aggregated and results disseminated. In 2003, the Ministry of Health, Labour and Welfare patient safety committee recommended a national reporting system.

The National Reporting and Learning System (NRLS) in England and Wales is another example of a learning system. NRLS receives reports of patient safety incidents from local health-care organizations.

For more details about the above systems, see Section 5.

Accountability systems

Reporting in accountability systems is usually mandatory and restricted to a list of defined serious events (also called "sentinel" events) such as unexpected death, transfusion reaction, and surgery on the wrong body part. Accountability systems typically prompt improvements by requiring an investigation and systems analysis ("root cause analysis") of the event. Few regulatory agencies have the resources to perform external investigations of more than a small fraction of reported events, however, which limits their capacity to learn. In Slovenia, a brief description of a sentinel event must be sent to the Ministry of Health within 48 hours, and 45 days later a satisfactory analysis with corrective actions must be submitted or else a follow-up consultation with the Ministry occurs. The Czech Republic has reporting requirements that follow from their accreditation standards.

The Netherlands has a two-tiered process. The Health Care Inspectorate, the agency accountable for taking actions against substandard performance, mandates hospitals to report adverse events that have led to death or permanent impairment. Other adverse events are reported voluntarily. There is interest in moving towards a more uniform blame-free reporting system to aggregate events nationally.

A number of states in the United States have reporting systems that require hospitals or other providers to report certain types of serious, usually preventable events (see Section 6).

Most accountability systems not only hold health-care organizations accountable by requiring that serious mishaps be reported, they provide disincentives to unsafe care through citations, penalties or sanctions. The effectiveness of these systems depends on the ability of the agency to induce health-care organizations to report serious events and to conduct thorough investigations.

Accountability systems can (and should) be learning systems if investigations are carried out and if the lessons learned are disseminated to all other providers by the agency. For example, the Danish Health Care System recently passed an Act on Patient Safety that requires health-care providers to report adverse events so information can be shared and aggregated for quality improvement.

Confidentiality and public access to data

Experience has shown that learning systems are most successful when reports are confidential and reporters do not feel at risk in sharing information about errors. Indeed, some feel it is only with such safe reporting systems that subtle system issues and the multitude of contributing factors will be uncovered. From a pragmatic standpoint, many believe that protecting the confidentiality of health-care organizations significantly enhances participation in reporting (1, 2).

However, some citizen advocacy groups have called for public disclosure of information uncovered during investigations of serious adverse events, asserting the public's right to know about these events. Surveys in the United States show that 62–73% of Americans believe that health-care providers should be required to make this information publicly available (3, 4). Nonetheless, all but three states in the United States have statutes that provide legal protection of confidentiality (5).

Internal reporting

Reports to an agency or other national body from a hospital or other health-care organization usually originate from a report within the institution. While such reports may merely reflect statutory requirements, an institution that values patient safety will have an internal reporting system that captures much more than that.

The objectives of an internal reporting system for learning are first, to identify errors and hazards, and then through investigation to uncover the underlying sys-

tems failures, with the goal of redesigning systems to reduce the likelihood of patient injury. The key conceptual point here, and the heart of a non-punitive approach to error reporting, is the recognition that adverse events and errors are symptoms of defective systems, not defects themselves. Reporting, whether retrospective (adverse events and errors) or prospective ("hazards", or "errors waiting to happen") provides the entry point into investigation and analysis of systems' defects, which, if skillfully done, can lead to substantial system improvements. Reporting is one way to get this type of information, but not the only way (see Section 4).

Ideally, internal reporting systems should go hand in hand with external reporting systems, by identifying and analysing events that warrant forwarding to external reporting agencies. Conversely, external reporting systems are most effective when they are an extension of internal systems.

Process

What is reported

Types of reports

Reporting systems may be open-ended and attempt to capture adverse events and close-calls along the entire spectrum of care delivery, or may focus on particular types of events, such as medication errors or pre-defined serious injuries. In general, focused reporting systems are more valuable for deepening the understanding of a particular domain of care than for discovering new areas of vulnerability. While these guidelines focus on reporting systems related to adverse events and medical errors, other types of health-related reporting systems focus on medical devices, epidemiological outcomes such as emergence of antimicrobial resistance, post-marketing medication surveillance, and specific areas such as blood transfusions.

Formats and processes vary from prescribed forms and defined data elements to free-text reporting. The system may allow for reports to be submitted via mail, telephone, electronically, or on the World Wide Web.

Types of events

Adverse events. An adverse events is an injury related to medical management, in contrast to a complication of disease (6).Other terms that are sometimes used are "mishaps", "unanticipated events" or "incidents", and "accidents". Most authorities caution against use of the term accident since it implies that the event was unpreventable.

Adverse events are not always caused by an error. For example, one form of adverse drug event, "adverse drug reaction" is, according to the WHO definition, a complication that occurs when the medication is used as directed and in the usual

dosage (7). Adverse drug reactions are, therefore, adverse drug events that are not caused by errors.

Many adverse events are caused by errors, either of commission or omission, and do, in fact, reflect deficiencies in the systems of care (8). Some reporting systems require that only preventable adverse events be reported, while others solicit reports whether or not a medical error occurred. One advantage of focusing reporting on adverse events rather than on errors is that it is usually obvious when a mishap has occurred; actual events focus attention.

Error. Error has been defined as "the failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning)" (9). Although reporting of errors, whether or not there is an injury, is sometimes done within institutions, if reporting of all errors is requested, the number may be overwhelming. Therefore, some sort of threshold is usually established – such as "serious" errors, or those with the potential for causing harm (also called "near misses" or "close calls"). Establishing such a threshold for a reporting system can be difficult. Hence, most "error reporting systems" are actually "adverse events caused by errors" systems.

"Near miss" or "close call". " A near miss" or "close call" is a serious error or mishap that has the potential to cause an adverse event, but fails to do so by chance or because it was intercepted. It is assumed (though not proven) that the underlying systems failures for near misses are the same as for actual adverse events. Therefore, understanding their causes should lead to systems design changes that will improve safety.

A key advantage of a near miss reporting system is that because there has been no harm the reporter is not at risk of blame or litigation. On the contrary, he or she may be deserving of praise for having intercepted an error and prevented an injury. This positive aspect of reporting of near misses, has led some to recommend near miss systems for internal reporting systems within health-care organizations or other health-care facilities where a blaming culture persists. However, any hospital that is serious about learning will also invite reports of near misses.

Hazards and unsafe conditions. Reporting of hazards, or "accidents waiting to happen" is another way to achieve prevention without the need to learn from an injury. If health care were as safe as some other industries, reports of hazards – potential causes of adverse events (as opposed to near misses, which are actual errors) – would outnumber those of actual events. Of all major systems, the Institute for Safe Medication Practices system for medication-related events has been most successful at capturing hazards (e.g. "look alike" packaging and "sound alike" names.) and calling for their remedy before a predictable error occurs.

Within a health-care organization, hazard reports raise alerts about unsafe conditions. Providers can imagine accidents waiting to happen based on their observations of weakness in the system and their experience as users. With appropriate analysis, these reports can provide valuable information for changes to systems design.

Who reports

Reporting systems must specify who files reports. In accountability systems, such as state health department systems and the JCAHO in the United States, reporting is done by the organization. Many also solicit and receive reports from caregivers (doctors and nurses). Some jurisdictions require caregivers to file reports. Some reporting systems allow patients, families and consumer advocates to report events. The latter are typically merely a notice that an event has occurred. In general, learning systems solicit reports from caregivers or organizations. Focused systems targeting specific areas such as medication errors or intensive care errors solicit reports from specialists such as pharmacists or intensive care specialists, while broad-based systems look to organizations and caregivers, but usually accept reports from anyone.

A potential source of reports that has not been significantly used is patients and families who have experienced medical error. Patients often report a high desire to see remedial action taken to prevent future harm to others. Reporting can initiate that process. Patients may report otherwise unidentified issues that help health-care organizations understand where the holes in their safety nets are, identify root causes, and mitigate harm. A patient may experience an injury that does not manifest until after discharge from a hospital and therefore is not otherwise captured. Patients may be better positioned than their care providers to identify failures in hand-overs and gaps between providers across the continuum of care.

How do they report

Method: e-mail, fax, Internet, mail, phone calls

Methods for submitting reports vary according to local infrastructure and technology. They can range from mailing written reports to a central address, to web-based systems that centralize and aggregate multiple reports into a highly structured database. Mail, fax, and phone calls are most widely used, since these mechanisms are widely available. A streamlined process can be set up to receive reports by e-mail or over the Internet; for users who have access to these technologies, this can be very quick and easy (although it may be costly to establish the technical infrastructure). Systems that use e-mail or the Internet must be able to provide technical support for users.

Structured forms or narrative text

Reports may be highly structured, requiring specific types of information, or provide for a narrative description of events for analysis. The extent to which datasets can be developed for analysis depends in part on the degree of standardization inherent in the data reported. Events based on commonly accepted data elements, such as the classification of medication errors into wrong medication, wrong dose, wrong frequency and so on, can be readily configured into a standardized reporting format.

A higher level of structured reporting asks reporters to select options from defined fields as part of the reporting process. This can greatly facilitate input into datasets developed for analysis. The Australian Patient Safety Foundation's Advanced Incident Management System (AIMS), offers a highly sophisticated customizable data entry form that guides users through a cascade of natural questions and response choices that are structured and consistent.

However, much of what promotes learning in patient safety lacks crisply defined data elements, so most authorities believe it is important for reports to include narrative to convey meaning. Narrative reports provide the opportunity to capture the rich context and storyline that allow the conditions that contributed to the error to be explored and understood. Indeed, some believe that only narrative reports are capable of providing information that provides meaningful insight into the nature of the underlying systems defects that caused the incident (Richard Cook, personal communication).

The vast majority of reporting forms have at least some room for a narrative description, and some, such as the United States Food and Drug Administration (FDA) MedWatch programme include open narrative for other relevant medical information such as laboratory data or patient condition.

Because of the nature of analysis that is required, systems that elicit open-ended, narrative texts require additional resources for data analysis and interpretation. In contrast, reports to systems with a standardized format, fixed fields, and predefined choices are swiftly entered and readily classified, making possible aggregated analysis at lower cost.

Another consideration is the effect of reporting on the reporter. Providing reporters with the chance to tell their stories implicitly values their observations. When the reporter can trust in a considered and non-punitive response, the process raises the individual's awareness of patient safety and sense of responsibility for reporting.

Classification

Reporting of events is of little value unless the data are analysed. Regardless of the objective of the system – whether to identify new and previously unsuspected hazards, discover trends, prioritize areas for remedial efforts, uncover common contributing factors, or develop strategies to decrease adverse events and patient harm – neither the act of reporting nor the collection of data will accomplish that objective unless the data are analysed and recommendations are made for change. Classification of the event is the first step in the analysis.

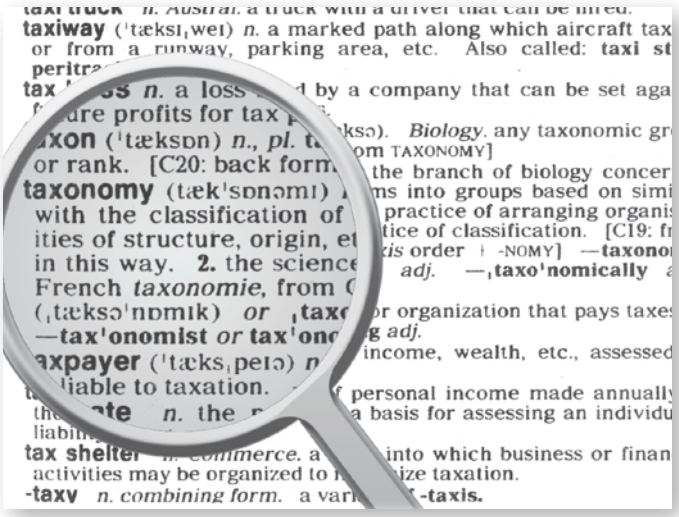
Why classify?

Recall the case presented in Section 1 of the inadvertent connection of oxygen tubing to an intravenous line the result being an air embolism. After the incident is reported, classification by the reporting system turns a specific event into an example that could happen anywhere; this particular incident becomes an example of "tubing mix-up". When aggregated with similar incidents, depending on the availability of contextual information, a variety of solutions can emerge, ranging from changes in nursing practice standards to a requirement for medical device manufacturers to develop incompatible connectors for all medical tubing. Classification starts the process of developing solutions that can be generalized.

Classification systems (taxonomies)

A number of quite different systems have been used for classifying patient safety incidents. These systems are also called "taxonomies". Because of differences between taxonomies, data can often not be shared among systems. Further, none have been validated, in the sense of studies that demonstrate that the classification and analysis method used leads to significant improvements in patient safety. As a result, the WHO World Alliance for Patient Safety has included in its Forward Programme 2005 an action area focusing on the development of an internationally agreed taxonomy of events.

Some of the factors that have been used to classify events include: error type (wrong dose, wrong diagnosis, etc.), patient outcome (level of harm, from none to death), setting, personnel involved, product or equipment failures, proximal (obvious) causes (misidentification of a patient), underlying causes (lack of knowledge, information, skills, etc.), contributing factors (organizational factors, environmental factors, etc.), stage in process of care (ordering, implementation, responding to laboratory results), and mechanism of error (knowledge-based, rule-based, skill-based). These taxonomies tend to fall into three major categories: classification by event, by risk, or by causation.


taxiway (ˈtæksɪˌweɪ) *n.* a marked path along which aircraft tax
or from a runway, parking area, etc. Also called: **taxi st**
taxonomy (tækˈsɒnəmɪ)
with the classification of
in this way. **2.** the science
French *taxonomie*, from
—**taxˈonomist** *or* **taxˈono**
axpayer (ˈtæksˌpeɪə) *n*
liable to taxation.
tax shelter
activities may be organized to
-taxy *n. combining form.*
practice of arranging organis
income, wealth, etc., assessed
personal income made annually
a basis for assessing an individu
into which business or finan
-taxis.

A taxonomy of adverse events classifies by event type, such as how many medication errors are attributable to "wrong dose" or "wrong patient". Event classification schemes work best when describing a specialized medical domain, such as medication errors, dialysis events or transfusion mismatches.

Several systems use taxonomies to assess risk, in order to prioritize events for action or to determine if further investigation is warranted. The United States Pharmacopoeia (USP) uses a nine-tier approach to rank medication risk. The Veterans Health Administration (VHA) uses a scoring system to prioritize both the potential severity, and the likelihood of occurrence of events, based on specific

scales and definitions; these are organized into a "safety assessment code" matrix (10). See Figure below.

The Australian Patient Safety Foundation uses explicit criteria for assessing the degree of risk expressed as a risk matrix that plots the severity of the outcome against the likelihood of its recurrence (11). The United States Agency for Healthcare Research and Quality (AHRQ) has indicated that a risk assessment scale should be included in its Patient Safety Network reporting system currently being developed in collaboration with the Institute of Medicine's Committee on Data Standards for Patient Safety

Figure: Safety Assessment Code (SAC) Matrix

		SEVERITY			
		Catastrophic	Major	Moderate	Minor
PROBABILITY	Frequent	16	12	8	4
	Occasional	12	9	6	3
	Uncommon	8	6	4	2
	Remote	4	3	2	1

Source: Veterans Health Administration National Center for Patient Safety, United States of America

The earliest classification system that focused on causation was the Eindhoven Classification Model, developed at Eindhoven University of Technology in the Netherlands. It is used in high-risk industries such as chemical manufacturing. It has recently been adapted for use in the VHA root cause analysis to identify factors based on the principles of human, organizational, and technical factors.

Another causation-oriented system is the Australian Incident Monitoring System developed by the Australian Patient Safety Foundation. This classification system comprises more than a million permutations of terms to describe an incident or adverse event. The system allows the end user to deconstruct an incident into a very detailed data set that defines the relationships between the component factors of the classification system.

A related system is classification by contributing factors, used at the Clinical Risk Unit at University College in London, England to identify patient, provider, team, task, work environment, organizational and other factors, through comprehensive systems analysis (12).

Design of a classification system

At least three key factors should be considered in the design of a classification system:

- The purpose of the reporting system. What is the expected product? How will the classification scheme facilitate analysis that will produce the desired outcome?
- The types of data that are available. Are reporters expected to have carried out an investigation and analysis of the event? If not, it is

unlikely that they will be able to provide useful information concerning underlying systems causes, and events will not be able to be classified at that level.

- Resources. The more detailed and elaborate the classification system is, the more expertise will be required, and the costlier the system will be to maintain.

A report commissioned by WHO and prepared by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) notes that the following attributes are desirable in an ideal classification scheme (13):

- It should address a broad and diverse range of patient safety issues and concerns across multiple health-care settings.
- It should identify high-priority patient safety data elements that are important to health-care systems.
- It should classify information related to what, where and how medical management goes wrong, the reasons why medical incidents occur, and what preventive and corrective strategies can be developed to keep them from occurring or to ameliorate their effects in health care.
- It must provide a meaningful and comprehensive linkage between the contributory factors and the errors and systems failures that lead to adverse events.
- It should facilitate the monitoring, reporting, and investigation of adverse events and near misses at the public health level – allowing aggregated data to be combined and tracked.

Because the resources required for taxonomy and analytical development tools are substantial, development of classification schemes is probably better left to national or international agencies rather than individual health-care systems.

The role of classification

Classification can be the cornerstone of what the system does. If the main goal is to produce data on the frequency of different types of events, as in the USP MedMARx^{SM} system, then performing the classification, determining frequencies, and feeding back that information may be all that is needed to meet the objective of the reporting system.

More commonly, classification is the beginning of more complex analysis, the first step. A direct link exists between the type and complexity of the classification scheme, and the level of analysis that is possible. That is, the analytic plan should determine the classification scheme, not the reverse.

Analysis

Hazard identification

At a minimum, a reporting system should permit identification of new and unsuspected hazards, such as previously unrecognized complications associated with use of a medication or a new device. A simple way this can be done is by direct human review of incoming reports. For example, if even a few people report that free flow protection on a particular pump model can fail, that may be sufficient for the receivers of the reports to recognize the problem, alert the providers and communicate directly with the pump manufacturer.

This type of analysis requires that knowledgeable experts review reports, but the reports do not need to be based on extensive investigation by the reporting organization. A good example of a hazard identification model is the Institute for Safe Medication Practice (ISMP) Medical Error Reporting Program, where a small group of pharmacists reviews all reports, identifies new hazards, and prioritizes them for action. Recommendations are then disseminated to the participants (most hospitals) every two weeks via a newsletter, Medication Safety Alert.

Both JCAHO, through its sentinel events alert warning and ISMP have legitimately taken credit for the success in removing concentrated potassium chloride from nursing units in the United States (14). ISMP alerts have also led to drug name and label changes, as well as the removal or restriction of the use of many drugs (15). MedMARx[SM] analysis revealed reports of three drugs with a high frequency of medication errors: insulin, heparin, and warfarin (16).

Summaries and descriptions

At the next level, a simple classification scheme can provide summaries and descriptions that permit determination of frequencies or ranking by order of frequency. An example of this would be a reporting system that records medication errors classified by dose, route, patient, etc. Calculating frequencies permits prioritization that can be used by focused systems to allocate further resources.

Trend and cluster analysis

Trend analysis, obtained by calculating and observing rates of events over time, can identify significant changes that suggest new problems (or, if improving, that safety measures are working). Trends can also be detected using statistical control methodologies. These assist a particular organization in discerning whether its own trends, when compared with benchmarks, are attributable to what is known as "special cause" variation, rather than stemming from normal process fluctuations.

A cluster of events that suddenly arises suggests a need for inquiry. It is important to note that trends or clusters identified by reporting systems are those of reported events, not those of the events themselves. For example, the JCAHO recently released a sentinel event alert concerning wrong site surgery when the rate of reports it received increased substantially over a two-year period. However, it acknowledged that only a small fraction of events are reported, so the data may not be representative. The United States Pharmacopeia (USP) MedMARxSM system analyses events to identify trends. Such trends may influence standard-setting practices. Large-scale reporting systems such as the National Reporting and Learning System, of the National Health Service in England, also provide pattern analysis and recognition of trends or clusters (17).

Correlations

While trends over time or control charts are ways of using the factor of time, other analytical methods are available for additional cofactors. To take the example of 'medication error – wrong patient', other factors captured may include, for example, the health-care setting (whether clinic or hospital), the patient diagnosis, or the age of the patient. These can be subjected to an analysis of correlations to evaluate the strength of the relationship between two variables, such as whether dosing errors occur more frequently among chemotherapy patients than among patients undergoing other treatments, or whether wrong patient medication errors are more highly correlated with elderly patients than with younger (and perhaps more alert) patients.

Risk analysis

With adequate data, a reporting system can develop valuable information about risk. With a large number of reports, estimations of the probability of recurrence of a specific type of adverse event or error can be calculated. Analysis of reported outcomes can also produce an estimate of the average severity of harm caused by the incident. The Safety Assessment Code of the United States Veterans Health Administration uses these two factors, probability of recurrence and severity, to calculate a score for prioritizing incidents for safety initiatives.

Causal analysis

When many factors are classified and coded along with the event, a more complex set of correlations and relationships among the factors can be considered and tested in the database. If causal factors such as workloads, communication, teamwork, equipment, environment, staffing and the like are included, then correlations among many cause and effect relationships can yield important insights into a health-care system's vulnerabilities.

Another analytical tool that can be applied to datasets with a rich set of cofactors is regression analysis, which assesses the predictive value of multiple factors upon

the outcome. For example, regression analysis can be used to investigate whether patient diagnosis is a predictive factor for dosing error. The major use for this analytical approach is to go beyond identifying relationships to hypothesis testing.

The sentinel event alerts issued by JCAHO include risk reduction strategies based on causal analyses submitted with reports, such as finding that medication errors attributable to illegible handwriting or poor communication are more common when abbreviations are used. Eliminating abbreviations has thus become one of the JCAHO patient safety goals for hospital accreditation.

Systems analysis

The ultimate aim of reporting is to lead to systems improvements by understanding the systems failures that caused the error or injury. At the organizational level, this requires investigation and interviews with involved parties to elicit the contributing factors and underlying design failures. A national reporting system must receive this level of information in order to identify common and recurring systems failures. For example, if analysts repeatedly find similar underlying systems defects in reports of a specific type of error, then remedial actions should focus on correction of that failure.

The Australian Patient Safety Foundation identified problems with valve-controlled flow and pressure occurring with anaesthetic machines. Query of the database provided a deconstruction of the malfunction types and suggested, among other things, that frequent maintenance and audible alarms on pressure relief valves could prevent these mishaps (18).

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4. ALTERNATIVE SOURCES OF INFORMATION FOR PATIENT SAFETY

Key messages

- **Reporting systems are clearly of value for learning from others' experience.**
- **Reporting systems do not provide a complete picture of risks, hazards and system vulnerabilities.**
- **There are other valuable sources of information that can be used within a health service and nationally to complement reporting.**
- **These options may present less expensive options than establishing national reporting systems.**

National or system-wide reporting systems are clearly of great value for learning from others' experience. Many adverse events occur rarely, and thus to observers in the institution may seem to be isolated (outlier) cases. Commonality and common causation only emerge with analysis of aggregated data. Similarly, demonstrating occurrence of serious events in respectable peer institutions helps counteract a typical response of "that could never happen here", which providers may genuinely feel when asked about a serious adverse event, such as amputation of the wrong leg.

However, there are other valuable sources of patient safety information that can be used at both the internal health-care organizational level and nationally. Many are much less expensive, and therefore constitute important options for states and health-care organizations that are unable to finance a large reporting system. They are worthy of consideration even for those with highly developed reporting systems. We look at internal options first.

Internal alternative sources of safety information

An effective internal reporting system is an essential component of a hospital patient safety programme. However, even a simple reporting system can be a significant expense. For many institutions, providing the financial resources and expertise required to establish a reporting system may be a burden, and may not be the wisest use of scarce funds. Another problem is compliance. Studies have repeatedly shown that many events are not captured by typical reporting systems. Personnel often fail

to make reports for a host of reasons: because they forget, are too busy, or think it is unimportant, or because the reporting does not lead to significant change. Too often, failure to report reflects a punitive environment in which it can be harmful to the reporter or colleagues to report.

Fortunately, reporting is not the only way to obtain information about hazards and systems defects. Hospital personnel – nurses, pharmacists, doctors, risk managers, and others – are a rich source of information that even well run reporting systems do not fully exploit. Medical records, laboratory reports, and other routinely collected data can also be used to find evidence of safety problems. Several methods that have been found useful for utilizing these resources are described in this section. In addition, several alternative methods for collecting data on quality and safety of care are described that do require more extensive resources but offer the promise of more complete and less intrusive data collection. These alternatives are presented in order of increasing resource intensity.

Safety WalkRounds

A "Safety WalkRound" is a process whereby a group of senior leaders visit areas of a health-care organization and ask front-line staff about specific events, contributing factors, near misses, potential problems, and possible solutions. The leaders then prioritize the events and the patient safety team develops solutions with the clinicians. The results are fed back to the staff (1).

The information gleaned in this process often has the solution embedded in the event description. Thus, this process can often result in prompt changes that improve care and safety. It also can lead to culture change, as the concerns of front-line staff are addressed and as front-line staff are engaged in continuous observation of hazards and solutions for discussion with senior leadership. Leadership walkrounds are a low-cost way to identify hazards of concern to front-line staff and make needed changes. They require no additional staff, equipment, or infrastructure.

Focus groups

Focus groups are facilitated discussions with staff or with patients and families to elicit insights, concerns, and perceptions in an open, learning environment. Most nurses, for example, are aware of hazards in their daily work, accidents "waiting to happen", and are willing to discuss them if given the opportunity. A few hours with front-line people can generate a safety improvement agenda that will keep a hospital busy for months.

Focus groups offer an opportunity for a very rich learning environment as members within the group discuss and develop ideas. While this method of information gathering cannot provide trends or benchmarks like a reporting system, it can identify both hazards and potential solutions that otherwise remain hidden.

Medical record review

Medical record review has historically been the major method for oversight of quality. While labour intensive, record review often provides the reviewer with the story and context in which to understand events. In addition, medical record review allows for evaluation of processes as well as outcomes, and can yield information about whether important processes occurred, such as communication, documentation, use of a checklist, or administration of an evidence-based therapy.

Record reviews may be explicit, in which the reviewer searches for specific types of data that define events (such as "failure to rescue") or implicit, in which a clinical expert makes a judgment as to whether an adverse event and/or error has occurred (such as failure to follow up a positive laboratory test). Record reviews have been the cornerstone of the major population-based studies that defined the extent of medical injury (2-6). They are also widely used to monitor progress in preventing adverse events when new safe practices are implemented.

The major limitations of record review are its cost, and variability of content. Aside from laboratory reports and orders, much of the content is determined by the subjective judgments of those who write notes. While serious adverse events are almost always mentioned, errors and underlying conditions almost never are. "Near misses" are rarely noted. Thus, records can be valuable for case finding, but provide only limited contextual information.

Focused review

Medical record reviews that focus on a specific type of event can identify critical points of care that represent widespread vulnerabilities. Focused reviews of adverse drug events, for example, might show that ordering medications for patients with renal impairment, managing anticoagulation, and tracking allergies are areas that warrant widespread, systematic improvements. A focused record review might reveal not only the incidence of wrong-site surgery, but also whether a site checklist was executed and a time-out took place during each operation. Other focused analyses might include identifying high complexity processes.

Failure modes and effects analysis

Adverse events can be viewed as the outcomes of vulnerable systems. In addition to acquiring information about the outcomes, or events, it is very helpful to learn about the vulnerabilities in the system and about possible solutions to buffer and strengthen the systems of care.

Failure modes and effects analysis (FMEA) is a widely used tool for proactively identifying process vulnerabilities. It begins by systematically identifying each step in the process and then searches out "failure modes", that is, noticing what could go wrong. The next step is to evaluate how the failure mode could occur, and what are the "effects" of this failure. If a failure mode could result in catastrophic effects, the

process must be corrected or buffered. The FMEA is a proactive tool, used to evaluate a new process, or an existing process for proposed design changes.

Screening

Screening is the use of routine data to identify a possible adverse event. It can be performed retrospectively, or in "real" time, either by analysis of traditional paper records or automatically by computer programs if patient clinical and laboratory data are available in electronic form. "Occurrence" screening identifies when a predefined event occurs, such as a return to the operating room within an admission or a readmission for the same problem.

Screening criteria are sometimes referred to as "triggers". When a screening criterion is met, further investigation, usually in person by an expert, is needed to determine whether an event has, in fact, occurred.

For example, laboratory data can be screened for out of range International Normalized Ratio (INR) results in patients taking warfarin. Records of patients with a positive screen – defined as values above or below a defined range – are then reviewed to determine if an episode of haemorrhage or thrombosis has occurred.

The Institute for Healthcare Improvement (IHI) has pioneered in the use of a "trigger tool" to retrospectively discover adverse drug events (ADE) (7). Records are searched for the presence of any of a list of highly sensitive indicators (such as prescribing a narcotic antidote or out of range INR). If the trigger is found, further investigations are carried out to determine if the ADE did in fact occur. This tool can be used both to assess the rate of selected ADEs and to measure progress when new safe practices are implemented.

Observation

The observation method for discovering errors consists first of a knowledgeable expert (such as a nurse or pharmacist) observing a process and writing down precisely the steps that are taken by the provider. This log is then compared with the written orders to identify deviations. Observational studies of nurse administration of medications in a large number of hospitals have shown high error rates (average 11% of doses) (8). The nurses were not aware of the errors which would, thus, not be captured in a reporting system.

The observation method is very labour-intensive, and therefore costly. However, it yields very rich data that facilitate understanding, not only about what events occur, but also about the processes and dynamics that affect the outcome. It is a tool that can be used intermittently, as resources permit, both to identify and understand systems breakdowns and to monitor improvement after changes are implemented.

Observing the hand-over during a transition between caregivers, for example, will yield not only whether there is an error, but also meaningful clues as to the barriers

and solutions. Observation can also identify areas where process designs such as standardization, simplification, and forcing functions may be useful to avoid harm.

External alternative sources of safety information

At the national or systems level, alternatives to reporting have not been widely employed. Medical record reviews have been occasionally used in random audits to identify adverse events and estimate frequency. Specific one-off studies, such as the Confidential Enquiries in the United Kingdom have served this function for several decades (9,10). This type of sampling can identify system weaknesses that require attention with much fewer resources than required by a reporting system. Several other methods of gathering safety data are available, as described below.

Malpractice claims analysis

Where frequent, as in the United States, malpractice claims can provide a rich source of data concerning a small number of serious events. When a serious incident occurs, risk managers typically start a patient file (called a claim, even if no litigation ever ensues) and promptly conduct an investigation, interviewing all personnel involved to understand and correctly document exactly what happened. This type of analysis, while much less sophisticated than a root cause or systems analysis carried out by experts, produces far more information than the usual hospital reporting systems.

Analysis of claims, for example, has identified the factors that increase the probability of a foreign body being retained following surgery and demonstrated the need for fail-safe follow-up systems to ensure that positive mammograms lead to biopsy (11).

The limitation of malpractice claims is their non-representativeness. However, they do provide data on events that are significant – serious injuries – as well as data that are typically much more comprehensive than provided to most reporting systems.

Surveillance

Surveillance systems collect specific case data, checking for predefined factors and outcomes on all patients in a defined category (such as those with infection). These systems can identify the prevalence of risk and risk factors for key events, as well as provide benchmarks for organizations and assist in monitoring progress.

One of the best examples of a surveillance system is the National Nosocomial Infections Surveillance System, a voluntary, confidential cooperative effort between the United States Centers for Disease Control and Prevention (CDC) and participating hospitals to identify hospital-acquired infections and create a national database that is used to understand the epidemiology of nosocomial infections and antibiotic

resistance trends, and to provide robust benchmarks for organizations to track their own performance (12,13).

Another form of surveillance focuses on review of hospital discharge diagnostic codes. A list has been developed in the United States by the Agency for Healthcare Research and Quality (AHRQ) of specific discharge codes, called Patient Safety Indicators (PSI), that are highly correlated with "problems that patients experience as a result of exposure to the healthcare system and that are likely amenable to prevention"(14). Examples include retention of foreign bodies, complications of anaesthesia, obstetric trauma, decubitus ulcers, and postoperative hip fracture. Hospitals can use the PSI to identify potential systems failures and to monitor improvement in safety. As the indicators are refined, it seems likely that they will be used in a national monitoring programme.

Routine data collection

A variant of surveillance on a much larger scale is exemplified by the United States Veterans Health Administration National Surgical Quality Improvement Program (NSQIP) (15). Trained surgical clinical nurse reviewers collect data on 129 clinical and outcome variables (including 30-day postoperative outcomes) for all major operations performed at each Veterans Health hospital. These data are electronically transmitted to a coordinating centre that uses predictive models to generate risk-adjusted predicted probability of death or complications for each patient.

Observed and expected ratios of complication rates and mortality are then calculated for each hospital and service for all major surgical procedures and for each of the subspecialties and fed back to each hospital, together with de-identified benchmark data from all institutions for comparison. A central committee annually reviews the data, commends low outliers, and issues warnings to high outliers. Recurrent high outlier status leads to review by regional authorities and, when indicated, site visits to assist hospitals in identifying and remedying deficiencies. Since inception of NSQIP, data for more than 1 million cases have been entered into the national database.

Over a ten-year period, 1991-2000, after implementation of NSQIP, surgical mortality decreased by 27% and complications by 45% (16). Programme leaders attribute most of these reductions to changes made by the hospitals in response to data feedback. The total cost of the program is US$ 4 million annually, approximately US$ 12 per case. The savings from reduced mortality and complications are several multiples of this expense; thus there is a net saving with this method.

The success of NSQIP in reducing adverse events and mortality can be attributed to five factors: (i) data collection is automatic part of the daily routine for all patients, not just those with complications; (ii) designated trained individuals are responsible for data collection; (iii) results are risk-adjusted; (iv) results are fed back to hospitals as site-specific data with peer hospital comparisons; (v) outcomes are monitored

by a central oversight authority with the power to conduct site visits and require changes. After initial resistance, these systems have been well-accepted by physicians and hospitals.

Routine data collection bodes well for ultimately replacing reporting as the primary source of safety information in the future. For highly developed health-care systems that have fully electronic medical records, automated data collection and analysis can provide continuous monitoring of quality and safety at a fraction of the cost of a reporting system. Similarly, automatic feed of data to a central authority (as in the Veterans Health system) can occur rapidly and inexpensively. In such a system "reporting" would be much less important, and full attention could be given to analysis and focused investigation of key events uncovered by the data analysis.

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5. NATIONAL REPORTING SYSTEMS

Key messages

- **Existing national reporting systems exhibit great variation in sponsorship, support, participation, and function.**
- **All of these reporting systems aim to improve patient safety.**
- **Reporting to most national systems is voluntary.**
- **A major issue for all reporting systems, public or private, mandatory or voluntary, is confidentiality.**

Existing national reporting systems exhibit great variation in sponsorship, support, participation, and function. Some, such as the National Reporting and Learning System (NRLS) in England and Wales, and those of Denmark, the Czech Republic, and Sweden were developed by governmental agencies to provide information to improve patient safety. Others, such as the Australian Incident Monitoring System (AIMS) sponsored by the Australia Patient Safety Foundation and the JCAHO Sentinel Events Reporting System, have been developed within the private or non-government sector.

All of these reporting systems aim to improve patient safety. However, their ability to do that varies considerably according to the sophistication of the analyses and the vigour with which efforts are pursued to turn insights into changes in practice. Patient safety is a relatively new concern for most governments. Not surprisingly, many still do not have a large cadre devoted to advancing safety or resources to carry out the plans they do make. A number of Member States have no current governmental initiatives in safety and no reporting system.

Reporting to most national systems is voluntary. However, systems in the Czech Republic and Slovenia require hospitals to report, and reporting of some especially serious events is required in the Netherlands, Japan, and other systems as well (see below for details).

Voluntary systems invite a professional ethic of participation in continuous learning and prevention, encouraged by acknowledgement and the reward of visible change. Experience from industries outside of health care, particularly aviation, as well as from some long-standing health-care reporting systems, for example, the Institute for Safe Medication Practice, shows that reporting systems are more likely to be successful if those reporting do not need to worry about adverse consequences to themselves or others.

A major issue for all reporting systems, public or private, mandatory or voluntary, is confidentiality. There is broad agreement across many systems that patients' and caregivers' names should not be disclosed, and these are protected by almost all systems. However there is much less agreement on whether the public should have access to hospital-level information.

Governmental health-care systems have a fiduciary responsibility to the public to ensure reasonable levels of safe care in health-care organizations, and reporting systems are one mechanism for discharging that responsibility.

Although accountability does not require release of all information, some form of public disclosure of adverse incidents seems indicated. Some systems make the events themselves available to the public; others disclose results of investigations or summary reports. Another option is to provide public notice of the occurrence of a serious event and of the actions taken in response by the institution and the government. Some agencies issue annual reports that summarize events and actions taken.

Types of patient safety reporting systems

The following information has been provided by representatives of reporting systems from across the world as a result of a survey undertaken for these guidelines.

Czech Republic

Type of reporting system: The Czech Republic has a mandatory reporting system. Voluntary reporting has also been in place for two years in 50 hospitals, and a national pilot project has been launched for voluntary reporting.

What is reported: Reportable events include nosocomial infections, adverse drug reactions, transfusion reactions, and medical equipment failures.

Who reports: Health care professionals.

How they report: Reports yield simple statistics of adverse events.

Analysis: Information is aggregated at different levels, including by hospital, medical specialization, region, and the republic. Analysis of sentinel event reporting in the field of acute hospital care launched in 2004; a similar project has been launched in long term care.

Response, dissemination and application of results: Reports are not accessible to the public.

Denmark

Type of reporting system: The Act on Patient Safety in the Danish Health Care System came into force January 1, 2004. The objective of the Act is to improve patient safety within the Danish health care system. The law obligates health care professionals to report specified adverse events to a national database. To support learning, this national mandatory system is sharply separated from the system of sanctions.

What is reported: Reportable adverse events are "events resulting from treatment by or stay in a hospital and not from the illness of a patient, if such event is at the same time either harmful, or could have been harmful had it not been avoided beforehand, or if the event did not occur for other reasons. Adverse events shall comprise events and errors known and unknown" Surgical events and medication errors, including close calls, must be reported.

Who reports: Healthcare professionals who become aware of an adverse event in connection with a patient's treatment or hospital stay are required to report the event.

How they report: Health care professionals report to the national database. Reports are automatically forwarded to the county where the event occurred and county councils record, analyse, and de-identify the reports. Lastly, reports are forwarded to the National Board of Health, which maintains a national register of adverse events.

Analysis: Although there are no national requirements for analysis, there is general use of the Safety Assessment Code (SAC) score. Adverse events with less serious SAC scores are acted upon locally, whereas serious adverse events (SAC score of three) prompt a root cause analysis.

Response, dissemination and application of results: Hospital owners are obligated by the Act on Patient Safety to act on reports, while the National Board of Health is charged with dissemination of lessons learnt. The National Board of Health issues alerts in the form of regular newsletters, in addition to an annual report.

Further information: www.patientsikkerhed.dk

England and Wales

Type of reporting system: The National Reporting and Learning System (NRLS) has been developed by the National Patient Safety Agency (NPSA) to promote an open reporting culture and a process for learning from adverse events. The purpose of the NRLS is to elicit reports of patient safety incidents, identify themes and patterns in the types of incidents being reported including major systems failures, and to develop and promote implementation of solutions.

The NRLS was launched in February 2004. As of July 2005, 548 NHS organizations have successfully connected to NRLS (90% of the total number).

What is reported: Patient safety incidents to be reported are defined as "any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded healthcare". Reports are anonymous, although a NHS Trust identifier is maintained; if staff or patient names are provided, they are removed before data are entered in the database.

Who reports: Any health care staff member can report a patient safety incident to the NRLS. The NPSA receives reports from NHS Trusts who in turn encourage reporting of patient safety incidents from each organization. The Trusts can be Acute, Primary Care, Mental Health or Ambulance Service oriented. Participation by health care services is voluntary.

How they report: Health care organizations with electronic risk management systems can use a technical link to submit reports directly from this local system into the NRLS. The NPSA has worked with local risk management software vendors to establish compatibility and interfaces. The objective is to have reports that are already collected for local use forwarded seamlessly to the national repository, therefore avoiding any duplication of data entry. Data are submitted to the NRLS at a rate of around 10,000 reports a week. The NSPA has worked with every Trust to 'map' its dataset to that of the NRLS (1).

The NPSA has also developed an electronic reporting form, the 'eForm', for use by organizations without compatible commercial risk management system software or for reports submitted independently of an organization's risk management system. The NRLS provides a detailed report form that guides the user through multiple question categories with coded options defining categories of where, when how, and what occurred. Brief sections for narratives are embedded throughout the form.

Patients and carers can telephone reports to the relevant Trusts' NHS Patient Advice and Liaison Service. Staff can also send in reports directly and plans exist to enable patients and from 2006 carers to report via an eForm.

Analysis: After data cleansing (the removal of identifying information), the NPSA database supports the identification of trends based on the specific data elements defined in the reporting formats. Standardized data are extracted that include the 'when and where', level of patient harm, patient characteristics, and contributing factors.

Adverse events are categorized into classes such as a medication event; these are further broken down into descriptors such as wrong quantity, wrong route, etc. The report form allows for narrative throughout, but the data provided in the structured, standardized format, can be automatically entered in the database and correlated to identify trends and relationships among the events and causes.

Reports are aggregated and analysed with expert clinical input to help understand the frequency of types of patient safety incidents, patterns and trends and underlying contributory factors. Investigation of reports submitted locally remains the responsibility of the local organizations. The NPSA does not investigate individual incidents or become involved in discipline or performance management.

Response, dissemination and application of results: Lessons learnt from NRLS are disseminated through the publication of NPSA Patient Safety Observatory reports and through feedback to reporting organizations on incident trends and solutions. Lessons learned from the NRLS feeds into the NPSA work on safety solutions.

Incident reports are not accessible to the public, but NHS Trusts may (and do) make information available at their discretion. The NPSA also provides root cause analysis training.

Further information: www.npsa.nhs.uk

The Netherlands

Type of reporting system: Non-punitive, voluntary reporting systems for adverse events are in place within most hospitals and other health care organizations. A mandatory system also exists for reporting serious adverse events (with permanent injury or death as result) which is monitored by the Health Care Inspectorate. There is considerable under-reporting.

What is reported: There is a legal requirement that serious adverse events are reported to the Health Care Inspectorate; adverse events resulting in persistent patient injury or death are reported, as well as suicides and acts of sexual harassment. Medical equipment failures are reported by manufacturers in accordance with legal European obligations.

Who reports: Voluntary reporting is conducted by anonymous sources, hospital or health care organizations, other health care organizations, patients, health care professionals and members of the public. Mandatory reporting is conducted by hospital or healthcare organizations, other health care organizations or by licensing or disciplinary actions.

How they report: Reports can be submitted by mail, fax, or phone.

Analysis: Data classification among the hospital systems is not standardized, meaning no national aggregation of data. The national mandatory system collates data.

As part of a regulatory response all hospitals are required to investigate serious events and redesign systems.

Response, dissemination and application of results: Following receipt of reports by the agency, most reports are investigated; receive analysis of incident causation and feedback to the reporter. The classification and collation of data is not solid and, therefore, may be unreliable. The Health Care Inspectorate received 2716 reports in 2003; average annual number of reports 3000. Committees for the investigation of adverse events in individual health care institutions are required to make an annual report. The Health Care Inspectorate produces an annual report of summary data which is made publicly available.

Further information: www.minvws.nl

Ireland

Type of reporting system: The Republic of Ireland established enterprise liability under a Clinical Indemnity Scheme (CIS) in 2002 to promote safe patient care, to reduce the number of claims and to manage claims in a timely fashion. A secure web based Clinical Incident Reporting System is being rolled out nationally.

What is reported: Reportable adverse incidents include "events arising as consequence of provision of, or failure to provide clinical care that results in injury, disease, disability, death or prolonged hospital stay for the patient" and "near misses".

Who reports: All enterprises covered by the CIS are required to report on a mandatory basis, all adverse clinical events and "near misses".

How they report: Paper reports are submitted to local risk management personnel. These data are then transmitted electronically to the Clinical Indemnity Scheme central database via a secure web based system (STARSweb).

Analysis: STARSweb enables aggregated statistical analysis and supports detection of trends both at the enterprise and national level.

Response, dissemination and application of results: Lessons learnt will be disseminated through quarterly newsletters, topic-based seminars, and via a regularly updated website.

Further information: www.dohc.ie

Slovenia

Type of reporting system: A voluntary national reporting system for sentinel events was established in 2002, similar to that developed by the Joint Commission on Accreditation of Healthcare Organizations in the United States.

What is reported: Sentinel events reported include: unexpected death; major permanent loss of function; suicide of a patient while in the hospital; discharge of a newborn infant to a wrong family; hemolytic transfusion reaction following administration of blood or blood products because of the incompatibility of major blood groups; surgery on a wrong patient or body part; and neglect which has a possible characteristic of a criminal offence.

Who reports: Hospitals

How they report: Reported information is analyzed at the Ministry of Health, who also provide an initial feedback to the health care organization where the error occurred.

Response, dissemination and application of results: Reports are accessible to the public as anonymous summaries disseminated via the internet.

Sweden

Type of reporting system: The Swedish healthcare law of 1997 requires every medical institution to have a quality system; most medical institutions have implemented different forms of quality systems, which are regulated by Statutes issued by the National Board of Health and Welfare (NBHW). The reporting and learning system is part of a regulatory response that requires hospitals to investigate serious events and redesign systems.

What is reported: Events resulting in unanticipated serious injury or disease or risk thereof are reported; this covers adverse events, near misses, equipment failures, suicide and other hazardous events.

Who reports: Reports are received from hospital and health care organizations and health care professionals.

Hospitals, heath care organization, licensing and disciplinary bodies are required to report adverse events to their nearest superior offices. Patients, health care professionals and members of the public voluntarily report events.

How they report: Reporting is done in paper format via mail or fax. The National Board of Health and Welfare receives reports; approximately 1100 mandatory and 2400 voluntary reports are received annually. The board investigates most reports and provides an analysis of incident causation; in all cases feedback is provided to the reporter.

Analysis: Regional supervisory units of the NBHW receive reports and carry out inspections. In a limited number of cases reports are sent to the Medical responsibility board (HSAN), where certified health care personnel may be subject to disciplinary actions.

Response, dissemination and application of results: The Board issues recommendations to influence statutes in order to promote patient safety.

All reports to the NBHW are accessible to the public, but all personal data about any patients involved are confidential.

United States of America

Type of reporting system: The United States does not have a national governmental reporting system, but 21 of the 50 state governments operate mandatory reporting systems. Many of these have been in place for decades. All 21 mandate reporting of unexpected deaths, and several mandate reporting of wrong-site surgery. Beyond this, definitions of reportable events vary widely. Reports of serious events may trigger on-site investigations by state health departments. Less serious reports usually do not elicit a visible response. States cite insufficient staff as a barrier to follow-up, education, consultation, and oversight. Some degree of public disclosure occurs in all states, but the degrees of protection and methods of public release of information vary considerably.

Private and non-government initiated systems

Australia - the Australian Incident Monitoring System (AIMS)

Type of reporting system: The Australian Incident Monitoring System (AIMS) was founded in 1993, as an extension of the Anesthesia AIMS, formed in 1987. The objectives of AIMS is to promote learning of new hazards, trends, risk factors and contributing factors.

What is reported: AIMS is designed to receive a wide range of events, including predefined "Sentinel" events, all adverse events, near misses, equipment failures, new hazards, and specific events such as suicide and abduction. AIMS can accept and classify incident information from any source including incident reports, sentinel events, root cause analysis, coroner's findings, consumer reports, and morbidity and mortality reviews.

Deliberately unsafe, abusive or criminal acts are not reported to AIMS but to mandatory reporting agencies.

Who reports: Reports are accepted from all sources, including hospitals, outpatient facilities, emergency departments, aged care (long term care), community care, professionals, patients and families, and anonymous sources.

The system is voluntary and confidential. By law, AIMS databases have been designated a formal quality assurance activity. This status confers protection from legal disclosure; revealing or disseminating individually-identifying information that becomes known solely as a result of safety and quality activities is a criminal offense.

Databases reside in a fully secure location with strictly limited access.

How they report: A single system (incorporating different forms) is used for all incidents. Reports are submitted by paper, electronically, or by phone.

Analysis: The classification system in AIMS is perhaps the most highly developed of any known reporting system, comprising more than a million permutations of terms to describe an incident or adverse event. The purpose of the classification process is to translate information about an incident into a common language and create an electronic record that can be compared with other records and can be analysed as part of a larger set of data. The latest classification is based on the Professor Runciman's Generic Reference Model (GRM). The GRM is based on the Reason model of complex system failure (2).

The GRM has the components contributing factors (environmental, organizational, human, subject of incident, agents), details of the incident (type, component, person involved, timing of the incident, timing of detection, method of detection, preventability), factors minimizing or aggravating outcomes or consequences, and outcomes for the patient and organization.

The GRM is implemented via Healthcare Incident Types (HITs). HITs are a series of cascading, hierarchically based questions and answers designed to "de-construct" the information in a way that facilitates subsequent analysis and learning.

AIMS allows the reporter to deconstruct an incident into a very detailed data set that can be used for analysis, aggregation, and trending. Owing to the rich "natural categories" in the classification scheme, interrelationships among event types, risk factors, and contributing causes can be probed.

A specific data module allows the user to develop a risk matrix to determine the severity of risk. Statistical correlations among the many elements in each category are explored to identify meaningful relationships and provide analysis that can generate insights into the overall systems of care.

AIMS has a hierarchically-based, completely customizable organization tree. All wards, departments, divisions, hospitals, health services, states or territories and nations can be represented. The organization tree has the potential for 13 levels.

Incidents can be analysed at the organization level and below at which the analyst has security rights (security constraints prevent analysts querying incidents above the organization node where they security privileges).The organization tree structure allows the whole spectrum of analysis from local management of problems to aggregated analysis at a national level. The AIMS system is well equipped to provide reports and queries on any term in the database, which makes it possible for institutions or departments to compare data.

Response, dissemination and application of results: The Australian Patient Safety Foundation provides newsletters, publications, and advice at a system level. The Health Departments who use AIMS also distribute information in the form of newsletters and publications.

Putting the information, trends, and recommendations into action is the responsibility of reporting facilities. Health care facilities and organizations are able to access AIMS findings from problem-specific task forces to lead patient safety initiatives.

Further information: www.apsf.net.au

Japan

Type of reporting system: In Japan, hospitals are mandated by the Ministry of Health, Labour and Welfare to have internal reporting systems. The Japan Council for Quality Health Care collects voluntary incident reports and implemented a national reporting system in 2004. Reporting to the new system is mandatory for teaching hospitals, voluntary for others

Reporting systems exist on three levels; hospital or health facility; voluntary system in several different forms such as accreditation body for hospitals and a research group, and at national level which is mandatory.

What is reported: Patient injuries, sometimes referred to as adverse events are reported along with near-misses and equipment failures.

Who reports: Reports are received from hospitals or health care organizations.

How they report: Any hospital or healthcare organization can voluntarily report to accrediting bodies. There is a mandatory requirement to report to the Japan Council for Quality Health Care. Information is reported electronically.

Analysis: The Agency will provide analysis of incident causation and feedback of analysis to the reporter. The data are classified and summary results are disseminated to healthcare providers and to the public.

Response, dissemination and application of results: Cases deemed particularly important are evaluated individually. Otherwise, reports are aggregated for statistical analysis (further details not available). The Japan Council for Quality Health Care produces summary reports of events and disseminates them to healthcare providers and to the public.

U.S.A. - Institute for Safe Medication Practices (ISMP)

Type of reporting system: ISMP is a national, confidential medication error reporting system. that distributes hazard alerts and other medication safety information to 600,000 providers every other week.

What is reported: ISMP is a focused reporting system for adverse drug events and hazards in medication delivery and management.

Who reports: Reports are accepted from health care professionals, organizations, or patients.

How they report: Reports from organizations or professionals can be submitted online, electronically, by telephone, mail, or fax.

Analysis: Over half of reporters are called back to elicit details about hazardous medication packaging or devices information of brand name, model number, or a photograph illustrating the problem This detailed information is extracted to enable specific, direct and immediate influence on hazard reduction. Medication information is classified according to 10 key elements. Hazard identification is done by human expertise; a group of experts observes recurrent reports, works closely together, and applies their knowledge to appreciate the urgency of a problem. Rapid turnaround permits numerous hazard alerts, so that an overall analysis for prioritization is unwarranted.

Response, dissemination and application of results: ISMP is engaged in numerous actions to support hazard reduction, such as promoting maximum dose statements on chemotherapy vial caps, elimination of pre-filled syringes for hazardous cardiac medications, identification and reduction of hazardous medical abbreviations among providers and pharmaceutical advertisements, and several other collaborations with pharmaceutical companies, device manufacturers, and the United States FDA.

Further information: www.ismp.org

U.S.A - Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

Type of reporting system: The Joint Commission on Accreditation of Healthcare Organizations implemented a Sentinel Event Reporting System in 1996. The system is designed to facilitate identification and learning among healthcare organizations of sentinel events and their prevention strategies. The system is voluntary and confidential. Accreditation status is not penalized for any organization that reports an error and applies due process to its future prevention.

What is reported: Reported sentinel events include: event has resulted in an unanticipated death or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition, or the event is one of the following (even if the outcome was not death or major permanent loss of function unrelated to the natural course of the patient's illness or underlying condition): suicide of any individual receiving care, treatment or services in staffed around-the-clock care setting or within 72 hours of discharge; unanticipated death of a full-term infant; abduction of any individual receiving care, treatment or services; discharge of an infant to the wrong family; rape; hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities; surgery on the wrong individual or wrong body part; unintended retention of a foreign object in an individual after surgery or other procedure.

Who reports:Reports are received from health care organizations and other sources such as media, complaints and the State Health Department.

How they report:Any accredited healthcare organization may submit reports.

Analysis: JCAHO require organizations to conduct a root cause analysis accompanied by an action plan. JCAHO also require access to review the organization's response to the sentinel event (which may or may not include actually reviewing the RCA). Guidance on conducting root cause analysis is offered by JCAHO on their website or upon request. Although reporting is voluntary, providing a root cause analysis is required.

Before the data describing the event, its root causes, and risk reduction strategies can be accepted into the database, the organization's response must meet certain defined criteria for acceptability.

Response, dissemination and application of results: Using their database and collaborating with experts, JCAHO periodically chooses a reported event type and develops a Sentinel Event Alert describing the events, causes, and strategies gathered from organizations for prevention. Publications began in 1998; to date 34 issues of Sentinel Event Alert have been published.

The individual organization's action plan is monitored by the JCAHO in a manner similar to the monitoring of corrective actions of other quality concerns. On a broader scale, hospitals' responses to the "Sentinel Event Alerts" are considered

during accreditation survey. The JCAHO have instituted National Patient Safety Goals as an influential derivative of the Sentinel Event reporting process.

Further information: www.jcaho.org

U.S.A - United States Pharmacopoeia MedMARx[SM]

Type of reporting system: MedMARx[SM] is a voluntary system designed to identify hazards and systems vulnerabilities, identify best practices, and gather information that will support the standard-setting activities of USP.

What is reported: Adverse drug events, near misses, and errors can all be submitted to MedMARx[SM].

Who reports: MedMARx[SM] accepts reports from healthcare professionals,organizati ons, and patients. Since its introduction in 1998, over 900 healthcare facilities have contributed over 630,000 medication error reports (Personal communication with J.Silverstone National Patient Safety Foundation email listserve, editor. 4-20-2004). Currently, they receive approximately 20,000 reports each month (Personal communication with D. Cousins 5-19-2004) or about 20 per month for each of their 900 healthcare facilities.

How they report: Reports can be submitted directly through a web-based portal, submitted electronically, or by telephone, mail, and fax.

Analysis: Reports are entered into a database that can be searched and used to count, sort, and correlate events.

Response, dissemination and application of results: USP analyzes the errors in MedMARx[SM] and provides an annual summary report. The database gathered by the USP is provided to the US Food and Drug Administration. A research partnership is underway with the Agency for Healthcare Research and Quality (AHRQ) to study the data for further improvement opportunities.

Further information: www.medmarx.com

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6. CHARACTERISTICS OF SUCCESSFUL REPORTING SYSTEMS

Key messages

A successful reporting and learning system to enhance patient safety should have the following characteristics:

- **reporting is safe for the individuals who report;**
- **reporting leads to a constructive response;**
- **expertise and adequate financial resources are available to allow for meaningful analysis of reports;**
- **the reporting system must be capable of disseminating information on hazards and recommendations for changes.**

The ultimate measure of the success of a reporting system is whether the information it yields is used appropriately to improve patient safety. How that is done varies greatly according to the aims of its sponsor. While both learning and accountability systems seek to improve learning from mistakes, the fiduciary objectives of the latter impose an additional constraint: satisfying the public's interest in making sure that known mechanisms for injury prevention are being used (rules and safe practices) and that new hazards are promptly addressed when they are uncovered. This may require some departure from the following concepts, particularly regarding confidentiality and independence.

Successful patient safety reporting systems have the following characteristics:

- reporting must be safe for the individuals who report;
- reporting is only of value if it leads to a constructive response, and meaningful analysis;
- learning requires expertise and adequate financial resources. The agency that receives reports must be capable of disseminating information and making recommendations for changes, and informing the development of solutions.

Table One lists the characteristics that have been identified by various authors as essential to the success of any reporting systems concerned with patient safety (1-4). Many of these characteristics are derived from long experience both in health care (for example, the Institute for Safe Medication Practice) and in other industries, particularly aviation. These essential characteristics are discussed below.

Non-punitive. The most important characteristic for success of a patient safety reporting system is that it must be non-punitive. Neither reporters nor others involved in the incidents can be punished as a result of reporting. For public systems, this requirement is the most difficult to achieve, since the public often assumes an individual is to blame, and there can be strong pressure to punish the "culprit". While perhaps temporarily emotionally satisfying, this approach is doomed to fail. People will not report any errors they can hide. It is important for national systems to protect reporters from blame. The best way to do this is by keeping the reports confidential.

Confidential. The identities of the patient and reporter must never be revealed to any third party. At the institutional level, confidentiality also refers to not making public specific information that can be used in litigation. Although, historically, breach of confidentiality has not been a problem in public or private systems, concern about disclosure is a major factor inhibiting reporting for many voluntary reporting programmes (5).

Independent. The reporting system must be independent of any authority with the power to punish the reporter or organization with a stake in the outcome. Maintaining a "firewall" between the reporting agency and the disciplinary agency in a governmental system can be difficult, but it is essential if trust in reporting is to be maintained.

Expert analysis. Reports must be evaluated by experts who understand the clinical circumstances under which the incidents occur and who are trained to recognize underlying systems causes. While it seems obvious that collecting data and not analysing it is of little value, the most common failure of governmentally run reporting systems is to require reporting but not to provide the resources needed to analyse the reports. Huge numbers of reports are collected only to sit in boxes or on computers. Expertise is a major, and essential, resource requirement for any reporting system.

Credible. The combination of independence and the use of content experts for analysis is necessary if recommendations are to be accepted and acted upon.

Timely. Reports must be analysed without delay, and recommendations must be promptly disseminated to those who need to know. When serious hazards are identified, notification should take place rapidly. For example, the Institute for Safe Medication Practice issues prompt alerts through its regular publication when new hazards in drugs are discovered.

Systems-oriented. Recommendations should focus on changes in systems, processes or products, rather than being targeted at individual performance. This is a cardinal principle of safety that must be reinforced by the nature of recommendations that come from any reporting system. It is based on the concept that even an apparently egregious individual error results from systems defects, and will recur with another person at another time if those systems defects are not remedied.

Responsive. For recommendations to result in widespread systems changes, the organization receiving reports must be capable of making and disseminating effective recommendations, and target organizations must make a commitment to implement recommendations. A good example is the National Reporting and Learning System in England and Wales which allows the National Patient Safety Agency to develop new solutions that are disseminated throughout the system.

Table 1 Characteristics of Successful Reporting Systems (7)

Non-punitive	Reporters are free from fear of retaliation against themselves or punishment of others as a result of reporting.
Confidential	The identities of the patient, reporter, and institution are never revealed.
Independent	The reporting system is independent of any authority with power to punish the reporter or the organization.
Expert analysis	Reports are evaluated by experts who understand the clinical circumstances and are trained to recognize underlying systems causes.
Timely	Reports are analysed promptly and recommendations are rapidly disseminated to those who need to know, especially when serious hazards are identified.
Systems-oriented	Recommendations focus on changes in systems, processes, or products, rather than being targeted at individual performance.
Responsive	The agency that receives reports is capable of disseminating recommendations. Participating organizations commit to implementing recommendations whenever possible.

Several of these characteristics are included among the attributes that Runciman has proposed for national reporting and learning systems (6):

- an independent organization to coordinate patient safety surveillance;
- agreed frameworks for patient safety and surveillance systems;
- common, agreed standards and terminology;
- a single, clinically useful classification for things that go wrong in health care;
- a national repository for information covering all of health care from all available sources;
- mechanisms for setting priorities at local, national and international levels;
- a just system which caters for the rights of patients, society, and health-care practitioners and facilities;
- separate processes for accountability and "systems learnings";
- the right to anonymity and legal privilege for reporters;
- systems for rapid feedback and evidence of action;
- mechanisms for involving and informing all stakeholders.

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7. REQUIREMENTS FOR A NATIONAL ADVERSE EVENT REPORTING AND LEARNING SYSTEM

Key messages

Certain capacities are needed for all reporting systems, whether simple or complex. These are:

- **clear objectives;**
- **clarity about who should report;**
- **clarity about what gets reported;**
- **mechanisms for receiving reports and managing the data;**
- **expertise for analysis;**
- **capacity to respond to reports;**
- **a method for classifying and making sense of reported events;**
- **the capacity to disseminate findings;**
- **technical infrastructure and data security.**

Before deciding whether to establish a national adverse event reporting and learning system, states should carefully consider (i) what the objectives of the system are (ii) whether they can develop the capacity to respond to reports; and (iii) the resources that will be required. It is also important to decide the scope of what is to be reported and the data to be collected.

Appendix 2 provides a quick reference checklist of issues to consider in developing a reporting system.

Objectives

Ideally, the objectives of a reporting system emerge from the perceived needs of a patient safety programme. Reporting is a tool for obtaining safety information. A national reporting system, therefore, can usefully be regarded as a tool to advance public policy concerning patient safety. It should be an extension of a programme

of quality improvement and error prevention. To be effective, learnings from the analysis of reports must feed into a mechanism for developing and disseminating changes in policy and practice that improve safety.

If the commitment to improvement is weak, or if there is no infrastructure to carry out implementation of changes, such as an agency charged with improving safety, a reporting system will be of little value. Stating it simply, it is more important to develop a response system than a reporting system. If there is a commitment to improvement of patient safety and some infrastructure, but resources are scant, alternative methods of identifying problem areas may be preferable (See Section 4).

Capacity to respond

Certain capacities are needed for all reporting systems, whether simple or complex. These are a mechanism for receiving the reports and managing the data, some capacity to get additional information, a technical infrastructure, a method for classifying events, expertise for analysis, and the capacity to disseminate findings.

Mechanism for collecting reports and database management

The optimal process for receiving, inputting, analysing, and disseminating reports will vary according to the specific objectives and focus of an individual reporting system. For example, a structured input can help with analysis, whereas story telling captures rich detail and context. Personal contact from phone calls or reading written reports engages the receiver with each report, whereas direct electronic transmission facilitates ease of use and direct database entry. Keeping in mind the essential objectives of the reporting system and considering available types of technical support and overall resources will help developers determine which methods are most suitable.

When reports are received by mail, phone, or fax, front-line staff must have a process for the initial sorting and triage of reports. Staff may be called upon to judge whether a report can be entered directly into the database, or requires forwarding to an internal expert for further understanding.

One advantage of reports being received by individuals (as opposed to automatic data transfer) is that staff may recognize that reports of certain types of events have recurred and then query the database to confirm a trend. Reporting systems that receive reports in this fashion require resources to perform data entry and manage the integrity of the database for organizing identifying information about each report.

Capacity to investigate

Even with simple systems that focus primarily on recognizing hazards, resources should be available to support follow-up on reports, provide feedback to the reporter, and conduct at least a limited investigation when indicated. More sophisticated systems will have the capacity to find out more about the context in which the event occurred and conduct a systems analysis or other process for understanding the clinical issues and systems flaws underlying the event. This may also require further discussions with the reporter or an on-site investigation. Experts who perform this function must be sufficiently familiar both with the clinical context and with systems principles to identify potential themes and extract the essential learnings from the event.

Technical infrastructure

The technical infrastructure required to support reporting systems may be very simple or quite sophisticated. Reporting systems that use phone, mail or fax require as a minimum an efficient method for communicating with internal or external experts, tracking the database and generating reports. Web-based systems offer ease of use to reporters and also eliminate the need for staff to do data entry. The technical infrastructure to enable entered reports to be downloaded into a database is most readily achieved with standardized data fields.

Finally, all systems must provide technical support to users who may require assistance, whether with paper forms or on-line reporting functions.

Method for classifying events

There are three key factors in determining what classification system should be used:

- the purpose of the reporting system, and thus the type of information desired and how the classification scheme will facilitate the purpose for which data are being collected;
- the nature of the data available since underlying systems causes cannot be included in a classification scheme if those data are not reported;
- Resources, bearing in mind that elaborate classification systems that require substantial expertise can be expensive.

Reporting systems with predefined events may have a minimal classification scheme that sorts events into simple categories. Such a scheme yields a count and possibly trends but provides little opportunity for further analysis.

A more sophisticated classification scheme will include categories such as causal factors, severity, probability of recurrence, and type of recovery. An ideal system will also obtain, and classify, information about contributing factors (see Section 3 for a detailed discussion of classification systems).

Expert analysis

Whether analysing relatively simple reports to identify and understand new hazards, or searching for common underlying contributing factors in serious adverse events, all reporting systems need experts who understand the content and context of reported events. Experts determine whether reports are for identifying trends only, require follow-up with the reporter for further information, should trigger an on-site investigation, or herald an emerging hazard that warrants alerting the health-care organizations.

To provide meaningful recommendations, it is necessary to have experts who understand the practice concerns, clinical significance, systems issues, and potential preventive measures for the problems raised by the reports. Ultimately, it is human experts who must translate the knowledge gleaned from aggregated reports into meaningful recommendations for action to improve care.

Capacity to disseminate findings and recommendations

To fulfill their mission, reporting systems must communicate back to the community from which the reports are received. Reports, newsletters, communications, or alerts distill the meaning of aggregated reports into meaningful themes, identify proposed actions to prevent harm, inform policy-makers of issues, broadcast solutions and best practices, or alert pharmaceutical companies, device manufacturers, or health-care providers to new hazards. This requires staff to write reports and a mechanism to disseminate reports, such as large-scale mailings, press releases, newsletters, or electronic bulletins.

At a higher level, findings from the reporting system inform new safety initiatives that are generated and implemented by the appropriate authority. The National Reporting and Learning System of England and Wales, for example, feeds information and recommendations to the National Patient Safety Agency, which develops initiatives and campaigns to implement solutions.

While ultimately the effectiveness of a reporting system is measured by improvements in clinical outcomes, an intermediary measure is the number of recommendations generated from analyses of reports.

Security issues

Whereas reports within a health-care organization often have rich detail and usually contain information that makes it possible to identify the people concerned, it is important that such information is removed from external reports and de-identified to protect patients, providers and reporters. Confidentiality protection against unauthorized access must be implemented with a data security system. This may include a process for de-identifying reports upon their receipt or after a follow-up

investigation has occurred. A lock box or "firewall" may be indicated to protect against inadvertent data sharing with other parties or agencies. Data encryption methods are essential for web-based reporting systems. Data security systems also should have a mechanism for identifying breaches of security.

8. RECOMMENDATIONS TO WHO MEMBER STATES

1. Adverse event reporting and learning systems should have as their main objective the improvement of patient safety through the identification of errors and hazards which may warrant further analysis and investigation in order to identify underlying systems factors.

2. When designing adverse event reporting and learning systems, the responsible parties should clearly set out:

- the objectives of the system
- who should report
- what gets reported
- mechanisms for receiving reports and managing the data
- sources of expertise for analysis
- the response to reports
- methods for classifying and making sense of reported events
- ways to disseminate findings
- technical infrastructure and data security.

3. Health-care workers and organizations should be encouraged to report a wide range of safety information and events.

4. Health-care workers who report adverse events, near misses and other safety concerns should not be punished as a result of reporting.

5. Reporting systems should be independent of any authority with power to punish the reporter.

6. The identities of reporters should not normally be disclosed to third parties.

7. Reported events should be analysed in a timely way.

8. Reported events should be analysed by experts who understand the clinical circumstances and care processes involved and who are trained to recognize underlying systems causes.

9. The entity that receives reports should be capable of making and disseminating recommendations. Participating organizations should agree to implement recommendations wherever possible.

10. Recommendations for preventative strategies should be rapidly disseminated, especially when serious hazards are identified.

APPENDIX 1
EXCERPT FROM INSTITUTE OF MEDICINE REPORT TO ERR IS HUMAN

Why Do Errors Happen?

The common initial reaction when an error occurs is to find and blame someone. However, even apparently single events or errors are due most often to the convergence of multiple contributing factors. Blaming an individual does not change these factors and the same error is likely to recur. Preventing errors and improving safety for patients require a systems approach in order to modify the conditions that contribute to errors. People working in health care are among the most educated and dedicated workforce in any industry. The problem is not bad people; the problem is that the system needs to be made safer.

This chapter covers two key areas. First, definitions of several key terms are offered. This is important because there is no agreed-upon terminology for talking about this issue.[1] Second, the emphasis in this chapter (and in this report generally) is about how to make systems safer; its primary focus is not on "getting rid of bad apples," or individuals with patterns of poor per-formance. The underlying assumption is that lasting and broad-based safety improvements in an industry can be brought about through a systems approach.

Finally, it should be noted that although the examples may draw more from inpatient or institutional settings, errors occur in all settings. The concepts presented in this chapter are just as applicable to ambulatory care, home care, community pharmacies, or any other setting in which health care is delivered.

This chapter uses a case study to illustrate a series of definitions and concepts in patient safety. After presentation of the case study, the chapter will define what comprises a system, how accidents occur, how human error contributes to accidents and how these elements fit into a broader concept of safety. The case study

will be referenced to illustrate several of the concepts. The next section will examine whether certain types of systems are more prone to accidents than others. Finally, after a short discussion of the study of human factors, the chapter summarizes what health care can learn from other industries about safety.

WHY DO ACCIDENTS HAPPEN?

Major accidents, such as Three Mile Island or the Challenger accident, grab people's attention and make the front page of newspapers. Because they usually affect only one individual at a time, accidents in health care delivery are less visible and dramatic than those in other industries. Except for celebrated cases, such as Betsy Lehman (the Boston Globe reporter who died from an overdose during chemotherapy) or Willie King (who had the wrong leg amputated),[2] they are rarely noticed. However, accidents are a form of information about a system.[3] They represent places in which the system failed and the breakdown resulted in harm.

The ideas in this section rely heavily upon the work of Charles Perrow and James Reason, among others. Charles Perrow's analysis of the accidentat Three Mile Island identified how systems can cause or prevent accidents.[4] James Reason extended the thinking by analyzing multiple accidents to examine the role of systems and the human contribution to accidents.[5] *"A system is a set of interdependent elements interacting to achieve a common aim. The elements may be both human and non-human (equipment, technologies, etc.)."*

Systems can be very large and far-reaching, or they can be more localized. In health care, a system can be an integrated delivery system, a centrally owned multihospital system, or a virtual system comprised of many different partners over a wide geographic area. However, an operating room or an obstetrical unit is also a type of system. Furthermore, any element in a system probably belongs to multiple systems. For example, one operating

An Illustrative Case in Patient Safety

Infusion devices are mechanical devices that administer intravenous solutions containing drugs to patients. A patient was undergoing a cardiac procedure. This patient had a tendency toward being hypertensive and this was known to the staff.

As part of the routine set-up for surgery, a nurse assembled three different infusion devices. The nurse was a new member of the team in the operating room; she had just started working at the hospital a few weeks before. The other members of the team had been working together for at least six months. The nurse was being very careful when setting up the devices because one of them was a slightly different model than she had used before.

Each infusion device administered a different medication that would be used during surgery. For each medication, the infusion device had to be programmed according to how much medication would flow into the patient (calculated as "cc's/hour"). The medications had different concentrations and each required calculation of the correct dose for that specific patient. The correct cc's/hour were programmed into the infusion devices.

The anesthesiologist, who monitors and uses the infusion devices during surgery, usually arrived for surgery while the nurse was completing her set-up of the infusion devices and was able to check them over. This particular morning, the anesthesiologist was running behind from a previous surgery. When he arrived in the operating room, the rest of the team was ready to start. The anesthesiologist quickly glanced at the set-up and accepted the report as given to him by the nurse.

One of the infusion devices was started at the beginning of surgery. About halfway through the surgery, the patient's blood pressure began to rise. The anesthesiologist

room is part of a surgical department, which is part of a hospital, which is part of a larger health care delivery system. The variable size, scope, and membership of systems make them difficult to analyze and understand.

In the case study, one of the systems used during surgery is the automated, medication adminstration system, which includes the equipment, the people, their interactions with each other and with the equipment, the procedures in place, and the physical design of the surgical suite in which the equipment and people function.

When large systems fail, it is due to multiple faults that occur together in an unanticipated interaction,[6] creating a chain of events in which the faults grow and evolve.[7] Their accumulation results in an accident. "An accident is an event that involves damage to a defined system that disrupts the ongoing or future output of that system." [8]

The *Challenger* failed because of a combination of brittle O-ring seals, unexpected cold weather, reliance on the seals in the design of the boosters, and change in the roles of the contractor and NASA. Individually, no one factor caused the event, but when they came together, disaster struck. Perrow uses a DEPOSE (Design, Equipment Procedures, Operators, Supplies and materials, and Environment) framework to identify the potential sources of failures. In evaluating the environment, some researchers explicitly include organizational design and characteristics.[9]

In the case study, the accident was a breakdown in the delivery of IV medicationsduring surgery.

The complex coincidences that cause systems to fail could rarely have been foreseen by the people involved. As a result, they are reviewed only in hindsight; however, knowing the outcome of an event influences how we assess past events.[10] Hindsight bias means that things that were not seen or understood at the time of the accident seem obvious in retrospect. Hindsight bias also misleads a reviewer into simplifying the causes of an accident,

tried to counteract this by starting one of the other infusion devices that had been set up earlier. He checked the drip chamber in the intravenous (IV) tubing and did not see any drips. He checked the IV tubing and found a closed clamp, which he opened. At this point, the second device signaled an occlusion, or blockage, in the tubing by sounding an alarm and flashing an error message. The anesthesiologist found a closed clamp in this tubing as well, opened it, pressed the re-start button and the device resumed pumping without further difficulty. He returned to the first device that he had started and found that there had been a free flow of fluid and medication to the patient, resulting in an overdose. The team responded appropriately and the patient recovered without further incident.

The case was reviewed two weeks later at the hospital's "morbidity and mortality" committee meeting, where the hospital staff reviews cases that encountered a problem to identify what happened and how to avoid a recurrence.

The IV tubing had been removed from the device and discarded. The bioengineering service had checked the pump and found it to be functioning accurately. It was not possible to determine whether the tubing had been inserted incorrectly into the device, whether the infusion rate had been set incorrectly or changed while the device was in use, or whether the device had malfunctioned unexpectedly. The anesthesiologist was convinced that the tubing had been inserted incorrectly, so that when the clamp was open the fluid was able to flow freely rather than being controlled by the infusion device. The nurse felt the anesthesiologist had failed to check the infusion system adequately before turning on the devices. Neither knew whether it was possible for an infusion device to have a safety mechansim built into it that would prevent free flows from happening.

highlighting a single element as the cause and overlooking multiple contributing factors. Given that the information about an accident is spread over many participants, none of whom may have complete information,[11] hindsight bias makes it easy to arrive at a simple solution or to blame an individual, but difficult to determine what really went wrong.

Although many features of systems and accidents in other industries are also found in health care, there are important differences. In most other industries, when an accident occurs the worker and the company are directly affected. There is a saying that the pilot is always the first at the scene of an airline accident. In health care, the damage happens to a third party; the patient is harmed; the health professional or the organization, only rarely. Furthermore, harm occurs to only one patient at a time; not whole groups of patients, making the accident less visible.*

In any industry, one of the greatest contributors to accidents is human error. Perrow has estimated that, on average, 60–80 percent of accidents involve human error. There is reason to believe that this is equally true in health. An analysis of anesthesia found that human error was involved in 82 percent of preventable incidents; the remainder involved mainly equipment failure.[12] Even when equipment failure occurs, it can be exacerbated by human error.[13] However, saying that an accident is due to human error is not the same as assigning blame. Humans commit errors for a variety of expected and unexpected reasons, which are discussed in more detail in the next two sections.

Understanding Errors

The work of Reason provides a good understanding of errors. He defines an error as the failure of a planned sequence of mental or physical activities to achieve its intended outcome when these failures cannot be attributed to chance.[14] It is important to note the inclusion of "intention." According to Reason, error is not meaningful without the consideration of intention. That is, it has no meaning when applied to unintentional behaviors because errors depend on two kinds of failure, either actions do not go as intended or the intended action is not the correct one. In the first case, the desired outcome may or may not be achieved; in the second case, the desired outcome cannot be achieved.

Reason differentiates between slips or lapses and mistakes. A slip or lapse occurs when the action conducted is not what was intended. It is an error of execution. The difference between a slip and a lapse is that a slip is observable and a lapse is not.

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* *Public health has made an effort to eliminate the term, "accident," replacing it with unintentional injuries, consistent with the nomenclature of the International Classification of Diseases. However, this report is not focused specifically on injury since an accident may or may not result in injury. See Institute of Medicine, Reducing the Burden of Injury, eds. Richard J. Bonnie, Carolyn Fulco and Catharyn Liverman. Washington, D.C., National Academy Press, 1999).*

For example, turning the wrong knob on a piece of equipment would be a slip; not being able to recall something from memory is a lapse.

In a mistake, the action proceeds as planned but fails to achieve its intended outcome because the planned action was wrong. The situation might have been assessed incorrectly, and/or there could have been a lack of knowl- edge of the situation. In a mistake, the original intention is inadequate; a failure of planning is involved.

In medicine, slips, lapses, and mistakes are all serious and can potentially harm patients. For example, in medicine, a slip might be involved if the physician chooses an appropriate medication, writes 10 mg when the intention was to write 1 mg. The original intention is correct (the correct medication was chosen given the patient's condition), but the action did not proceed as planned. On the other hand, a mistake in medicine might involve selecting the wrong drug because the diagnosis is wrong. In this case, the situation was misassessed and the action planned is wrong. If the terms "slip" and "mistake" are used, it is important not to equate slip with "minor." Patients can die from slips as well as mistakes. For this report, *error is defined as the failure of a planned action to be completed as intended (e.g., error of execution) or the use of a wrong plan to achieve an aim (e.g., error of planning)*. From the patient's perspective, not only should a medical intervention proceed properly and safely, it should be the correct intervention for the particular condition. This report addresses primarily the first concern, errors of execution, since they have their own epidemiology, causes, and remedies that are different from errors in planning. Subsequent reports from the Quality of Health Care in America project will consider the full range of quality-related issues, sometimes classified as overuse, underuse and misuse.[15]

Latent and Active Errors

In considering how humans contribute to error, it is important to distinguish between active and latent errors.[16] *Active errors occur at the level of the frontline operator, and their effects are felt almost immediately. This is sometimes called the sharp end.*[17] *Latent errors tend to be removed from the direct control of the operator and include things such as poor design, incorrect installation, faulty maintenance, bad management decisions, and poorly structured organizations*. These are called the blunt end. The active error is that the pilot crashed the plane. The latent error is that a previously undiscovered design malfunction caused the plane to roll unexpectedly in a way the pilot could not control and the plane crashed

In the case study, the active error was the free flow of the medication from the infusion device.

Latent errors pose the greatest threat to safety in a complex system because they are often unrecognized and have the capacity to result in multiple types of active errors. Analysis of the Challenger accident traced contributing events back nine years. In the Three Mile Island accident, latent errors were traced back two years.[18] Latent errors can be difficult for the people working in the system to notice since the errors may be hidden in the design of routine processes in computer programs or in the structure or management of the organization. People also become accustomed to design defects and learn to work around them, so they are often not recognized.

In her book about the *Challenger* explosion, Vaughan describes the "normalization of deviance" in which small changes in behavior became the norm and expanded the boundaries so that additional deviations became acceptable.[19] When deviant events become acceptable, the potential for errors is created because signals are overlooked or misinterpreted and accumulate without being noticed.

Current responses to errors tend to focus on the active errors by punishing individuals (e.g., firing or suing them), retraining or other responses aimed at preventing recurrence of the active error. Although a punitive response may be appropriate in some cases (e.g., deliberate malfeasance), it is not an effective way to prevent recurrence. Because large system failures represent latent failures coming together in unexpected ways, they appear to be unique in retrospect. Since the same mix of factors is unlikely to occur again, efforts to prevent specific active errors are not likely to make the system any safer.[20]

In our case study, a number of latent failures were present:

- *Multiple infusion devices were used in parallel during this cardiac surgery. Three devices were set up, each requiring many steps. each step in the assembly presents a possibility for failure that could disrupt the entire system.*
- *Each of the three different medications had to be programmed into the infusion device with the correct dose for that patient.*
- *Possible scheduling problems in the operating suites may have contributed to the anesthesiologist having insufficient time to check the devices before surgery.*
- *A new nurse on the team may have interrupted the "normal" flow between the team members, especially communication between the anesthesiologist and the nurse setting up the devices. There was no standardized list of checks between the nurse and anesthesiologist before starting the procedure.*
- *Training of new team members may be insufficient since the nurse found herself assembling a device that was a slightly different model. As a new employee, she may have been hesitant to ask for help or may not have known who to ask.*

Focusing on active errors lets the latent failures remain in the system, and their accumulation actually makes the system more prone to future failure. [21] Discovering and fixing latent failures, and decreasing their duration, are likely to have a greater

effect on building safer systems than efforts to minimize active errors at the point at which they occur.

In the case study, a typical response would have been to retrain the nurse on how to assemble the equipment properly. However, this would have had no effect on weaknesses in equipment design, team management and communications, scheduling problems, or orienting new staff. Thus, free flow errors would likely recur.

Understanding Safety

Most of this chapter thus far has drawn on Perrow's normal accident theory, which believes that accident are inevitable in certain systems. Al- though they may be rare, accidents are "normal" in complex, high technology industries. In contrast to studying the causes of accident and errors, other researchers have focused on the characteristics that make certain industries, such as military aircraft carriers or chemical processing, highly reliable.[22] High reliability theory believes that accidents can be prevented through good organizational design and management.[23] Characteristics of highly reliable industries include an organizational commitment to safety, high levels of redundancy in personnel and safety measures, and a strong organizational culture for continuous learning and willingness to change.[24] Correct performance and error can be viewed as "two sides of the same coin."[25] Although accidents may occur, systems can be designed to be safer so that accidents are very rare.

The National Patient Safety Foundation has defined patient safety as the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the processes of health care.[26] Safety does not reside in a person, device or department, but emerges from the interactions of components of a system. Others have specifically examined pharmaceutical safety and defined it to include maximizing therapeutic benefit, reducing risk, and eliminating harm.[27] That is, benefit relates to risk. Other experts have also defined safety as a relative concept. Brewer and Colditz suggest that the acceptability of an adverse event depends on the seriousness of the underlying illness and the availability of alternative treatments.[28] The committee's focus, however, was not on the patient's response to a treatment, but rather on the ability of a system to deliver care safely. From this perspective, the committee believes that there is a level of safety that can and should be ensured. Safety is relative only in that it continues to evolve over time and, when risks do become known, they become part of the safety requirements.

Safety is more than just the absence of errors. Safety has multiple dimensions, including the following:

- an outlook that recognizes that health care is complex and risky and that solutions are found in the broader systems context;

- a set of processes that identify, evaluate, and minimize hazards and are continuously improving, and
- an outcome that is manifested by fewer medical errors and minimized risk or hazard.[29]

For this report, safety is defined as freedom from accidental injury. This simple definition recognizes that from the patient's perspective, the primary safety goal is to prevent accidental injuries. If an environment is safe, the risk of accidents is lower. Making environments safer means looking at processes of care to reduce defects in the process or departures from the way things should have been done. Ensuring patient safety, therefore, involves the establishment of operational systems and processes that increase the reliability of patient care.

ARE SOME TYPES OF SYSTEMS MORE PRONE TO ACCIDENTS?

Accidents are more likely to happen in certain types of systems. When they do occur, they represent failures in the way systems are designed. The primary objective of systems design ought to be to make it difficult for accidents and errors to occur and to minimize damage if they do occur.[30]

Perrow characterizes systems according to two important dimensions: complexity and tight or loose coupling.[31] Systems that are more complex and tightly coupled are more prone to accidents and have to be made more reliable.[32] In Reason's words, complex and tightly coupled systems can "spring nasty surprises."[33]

In complex systems, one component of the system can interact with multiple other components, sometimes in unexpected or invisible ways. Although all systems have many parts that interact, the problem arises when one part serves multiple functions because if this part fails, all of the dependent functions fail as well. Complex systems are characterized by specialization and interdependency. Complex systems also tend to have multiple feedback loops, and to receive information indirectly, and because of specialization, there is little chance of substituting or reassigning personnel or other resources.

In contrast to complex systems, linear systems contain interactions that are expected in the usual and familiar production sequence. One component of the system interacts with the component immediately preceding it in the production process and the component following it. Linear systems tend to have segregated subsystems, few feedback loops, and easy substitutions (less specialization).

An example of complexity is the concern with year 2000 (Y2K) computer problems. A failure in one part of the system can unexpectedly interrupt other parts, and all of the interrelated processes that can be affected are not yet visible. Complexity is also the reason that changes in long-standing production processes must be made cautiously.[34] When tasks are distributed across a team, for example, many interac-

tions that are critical to the process may not be noticed until they are changed or removed.

Coupling is a mechanical term meaning that there is no slack or buffer between two items. Large systems that are tightly coupled have more timedependent processes and sequences that are more fixed (e.g., y depends on x having been done). There is often only one way to reach a goal. Compared to tightly coupled systems, loosely coupled systems can tolerate processing delays, can reorder the sequence of production, and can employ alternative methods or resources.

All systems have linear interactions; however, some systems additionally experience greater complexity. Complex interactions contribute to accidents because they can confuse operators. Tight coupling contributes to accidents because things unravel too quickly and prevent errors from being intercepted or prevent speedy recovery from an event.[35] Because of complexity and coupling, small failures can grow into large accidents.

In the case study, the medication adminstration system was both complex and tightly coupled. The complexity arises from three devices functioning simultaneously, in close proximity, and two having problems at the same time. The tight coupling arises from the steps involved in making the system work properly, from the steps required to assemble three devices, to the calculation of correct medication dosage levels, to the operation of multiple devices during surgery, to the responses when alarms start going off.

Although there are not firm assignments, Perrow considered nuclear power plants, nuclear weapons handling, and aircraft to be complex, tightly coupled systems.[36] Multiple processes are happening simultaneously, and failure in one area can interrupt another. Dams and rail transportation are considered tightly coupled because the steps in production are closely linked, but linear because there are few unexpected interactions. Universities are considered complex, but loosely coupled, since the impact of a decision in one area can likely be limited to that area.

Perrow did not classify health care as a system, but others have suggested that health care is complex and tightly coupled.[37] The activities in the typical emergency room, surgical suite, or intensive care unit exemplify complex and tightly coupled systems. Therefore, the delivery of health care services may be classified as an industry prone to accidents.[38]

Complex, tightly coupled systems have to be made more reliable.[39] One of the advantages of having systems is that it is possible to build in more defenses against failure. Systems that are more complex, tightly coupled, and are more prone to accidents can reduce the likelihood of accidents by simplifying and standardizing processes, building in redundancy, developing backup systems, and so forth.

Another aspect of making systems more reliable has to do with organizational design and team performance. Since these are part of activities within organizations, they are discussed in Chapter 8.

Conditions That Create Errors

Factors can intervene between the design of a system and the production process that creates conditions in which errors are more likely to happen. James Reason refers to these factors as psychological precursors or preconditions.[40] Although good managerial decisions are required for safe and efficient production, they are not sufficient. There is also a need to have the right equipment, well-maintained and reliable; a skilled and knowledgeable workforce; reasonable work schedules, well-designed jobs; clear guidance on desired and undesired performance, et cetera. Factors such as these are the precursors or preconditions for safe production processes.

Any given precondition can contribute to a large number of unsafe acts. For example, training deficiencies can show up as high workload, undue time pressure, inappropriate perception of hazards, or motivational difficulties.[41] Preconditions are latent failures embedded in the system. Designing safe systems means taking into account people's psychological limits and either seeking ways to eliminate the preconditions or intervening to minimize their consequences. Job design, equipment selection and use, operational procedures, work schedules, and so forth, are all factors in the production process that can be designed for safety.

One specific type of precondition that receives a lot of attention is technology. The occurrence of human error creates the perception that humans are unreliable and inefficient. One response to this has been to find the unreliable person who committed the error and focus on preventing him or her from doing it again. Another response has been to increase the use of technology to automate processes so as to remove opportunities for humans to make errors. The growth of technology over the past several decades has contributed to system complexity so this particular issue is highlighted here.

Technology changes the tasks that people do by shifting the workload and eliminating human decision making.[42] Where a worker previously may have overseen an entire production process, he or she may intervene now only in the last few steps if the previous steps are automated. For example, flying an aircraft has become more automated, which has helped reduce workload during nonpeak periods. During peak times, such as take-off and landing, there may be more processes to monitor and information to interpret.

Furthermore, the operator must still do things that cannot be automated. This usually involves having to monitor automated systems for rare, abnormal events[43] because machines cannot deal with infrequent events in a constantly changing environment.[44] Fortunately, automated systems rarely fail. Unfortunately, this means that

operators do not practice basic skills, so workers lose skills in exactly the activities they need in order to take over when something goes wrong.

Automation makes systems more "opaque" to people who manage, maintain, and operate them.[45] Processes that are automated are less visible because machines intervene between the person and the task. For example, automation means that people have less hands-on contact with processes and are elevated to more supervisory and planning tasks. Direct information is filtered through a machine (e.g., a computer), and operators run the risk of having too much information to interpret or of not getting the right information.

In the case study, the infusion device administered the medication and the professional monitored the process, intervening when problems arose. The medication administration process was "opaque" in that the device provided no feedback to the user when the medication flowed freely and minimal feedback when the medication flow was blocked.

One of the advantages of technology is that it can enhance human performance to the extent that the human plus technology is more powerful than either is alone.[46] Good machines can question the actions of operators, offer advice, and examine a range of alternative possibilities that humans cannot possibly remember. In medicine, automated order entry systems or decision support systems have this aim. However, technology can also create new demands on operators. For example, a new piece of equipment may provide more precise measurements, but also demand better precision from the operator for the equipment to work properly.[47] Devices that have not been standardized, or that work and look differently, increase the likelihood of operator errors. Equipment may not be designed using human factors principles to account for the human–machine interface.[48]

In the case study, safer systems could have been designed by taking into consideration characteristics of how people use machines and interact with each other in teams. For example:

- *Redesign the devices to default to a safe mode*
- *Reduce the difficulties of using multiple devices simultaneously*
- *Minimize the variety of equipment models purchased*
- *Implement clear procedures for checking equipment, supplies, etc., prior to beginning surgery*
- *Orient and train new staff with the team(s) with which they will work*
- *Provide a supportive environment for identifying and communicating about errors for organizational learning and change to prevent errors.*

Technology also has to be recognized as a "member" of the work team. When technology shifts workloads, it also shifts the interactions between team members.

Where processes may have been monitored by several people, technology can permit the task to be accomplished by fewer people. This affects the distributed nature of the job in which tasks are shared among several people and may influence the ability to discover and recover from errors.[49]

In this context, technology does not involve just computers and information technology. It includes "techniques, drugs, equipment and procedures used by health care professionals in delivering medical care to individuals and the systems within which such care is delivered."[50] Additionally, the use of the term technology is not restricted to the technology employed by health care professionals. It can also include people at home of differentages, visual abilities, languages, and so forth, who must use different kinds of medical equipment and devices. As more care shifts to ambulatory and home settings, the use of medical technology by non-health professionals can be expected to take on increasing importance.

RESEARCH ON HUMAN FACTORS

Research in the area of human factors is just beginning to be applied to health care. It borrows from the disciplines of industrial engineering and psychology. *Human factors is defined as the study of the interrelationships between humans, the tools they use, and the environment in which they live and work.*[51]

In the context of this report, a human factors approach is used to under- stand where and why systems or processes break down. This approach examines the process of error, looking at the causes, circumstances, conditions, associated procedures and devices and other factors connected with the event. Studying human performance can result in the creation of safer systems and the reduction of conditions that lead to errors. However, not all errors are related to human factors. Although equipment and materials should take into account the design of the way people use them, human factors may not resolve instances of equipment breakdown or material failure.

Much of the work in human factors is on improving the human–system interface by designing better systems and processes.[52] This might include, for example, simplifying and standardizing procedures, building in redundancy to provide backup and opportunities for recovery, improving communications and coordination within teams, or redesigning equipment to improve the human–machine interface.

Two approaches have typically been used in human factors analysis. The first is critical incident analysis. Critical incident analysis examines a significant or pivotal occurrence to understand where the system broke down, why the incident occurred, and the circumstances surrounding the incident.[53] Analyzing critical incidents, whether or not the event actually leads to a bad outcome, provides an

understanding of the conditions that produced an actual error or the risk of error and contributing factors.

In the case study, researchers with expertise in human factors could have helped the team investigate the problem. They could examine how the device performed under different circumstances (e.g., what the alarms and displays did when the medication flow changed), varying the setup and operation of the infusion device to observe how it performed under normal and abnormal conditions. They could observe how the staff used the particular infusion device during surgery and how they interacted with the use of multiple infusion devices.

A critical incident analysis in anesthesia found that human error was involved in 82 percent of preventable incidents. The study identified the most frequent categories of error and the riskiest steps in the process of administering anesthesia. Recommended corrective actions included such things as labeling and packaging strategies to highlight differences among anesthesiologists in the way they prepared their workspace, training issues for residents, work–rest cycles, how relief and replacement processes could be improved, and equipment improvements (e.g., standardizing equipment in terms of the shape of knobs and the direction in which they turn).

Another analytic approach is referred to as "naturalistic decision making."[54] This approach examines the way people make decisions in their natural work settings. It considers all of the factors that are typically controlled for in a laboratory-type evaluation, such as time pressure, noise and other distractions, insufficient information, and competing goals. In this method, the researcher goes out with workers in various fields, such as firefighters or nurses, observes them in practice, and then walks them through to reconstruct various incidents. The analysis uncovers the factors weighed and the processes used in making decisions when faced with ambiguous information under time pressure.

In terms of applying human factors research, David Woods of Ohio State University describes a process of reporting, investigation, innovation, and dissemination (David Woods, personal communication, December 17, 1998). Reporting or other means of identifying errors tells people where errors are occurring and where improvements can be made. The investigation stage uses human factors and other analyses to determine the contributing factors and circumstances that created the conditions in which errors could occur. The design of safer systems provides opportunities for innovation and working with early adopters to test out new approaches. Finally, dissemination of innovation throughout the industry shifts the baseline for performance. The experience of the early adopters redefines what is possible and provides models for implementation. Aviation has long analyzed the role of human factors in performance. The Ames Research Center (part of the National Aeronautics and Space Administration) has examined areas related to information technology, automation,

and the use of simulators for training in basic and crisis skills, for example. Other recent projects include detecting and correcting errors in flight; interruptions, distractions and lapses of attention in the cockpit; and designing information displays to assist pilots in maintaining awareness of their situation during flight.[55]

SUMMARY

The following key points can be summarized from this chapter.

1. Some systems are more prone to accidents than others because of the way the components are tied together. Health care services is a complex and technological industry prone to accidents.
2. Much can be done to make systems more reliable and safe. When large systems fail, it is due to multiple faults that occur together.
3. One of the greatest contributors to accidents in any industry including health care, is human error. However, saying that an accident is due to human error is not the same as assigning blame because most human errors are induced by system failures. Humans commit errors for a variety of known and complicated reasons.
4. Latent errors or system failures pose the greatest threat to safety in a complex system because they lead to operator errors. They are failures built into the system and present long before the active error. Latent errors are difficult for the people working in the system to see since they may be hidden in computers or layers of management and people become accustomed to working around the problem.
5. Current responses to errors tend to focus on the active errors. Although this may sometimes be appropriate, in many cases it is not an effective way to make systems safer. If latent failures remain unaddressed, their accumulation actually makes the system more prone to future failure. Discovering and fixing latent failures and decreasing their duration are likely to have a greater effect on building safer systems than efforts to minimize active errors at the point at which they occur.
6. The application of human factors in other industries has successfully reduced errors. Health care has to look at medical error not as a special case of medicine, but as a special case of error, and to apply the theory and approaches already used in other fields to reduce errors and improve reliability.[56]

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APPENDIX 2
CHECKLIST FOR DEVELOPING A REPORTING SYSTEM

1. Clarify objectives

- Learning
- Accountability
- Both

2. What types of learning are the priorities?

- Alerts regarding significant new hazards
- Lessons learned by hospitals
- Analysis of trends
- Analysis of systems failures
- Recommendations for best practices

3. Voluntary or mandatory?

- Voluntary
- Mandatory

4. Confidential or public disclosure?

- Confidential
- Public disclosure of individual reports
- Public disclosure of analysis or trends

5. What is the process for the reporting system?

- What is reported?
- Who can report?
- How does one report?

6. Is confidential information held secure?

- Patient confidentiality
- Reporter confidentiality
- Organization confidentiality

7. What is the data infrastructure?

- Human receiver recognizing hazard reports
- Simple spreadsheet
- Relational database

8. What is the approach to classification?

- By event type
- By risk
- By causation

9. What is the approach to analysis?

- Hazard identification
- Summaries and descriptions
- Trend and cluster analysis
- Correlations
- Risk analysis
- Causal analysis
- Systems analysis

10. How will responses be generated and disseminated?

- Acknowledgement to reporter
- Alerts generated to organizations
- Trends, themes, or best practices in periodic newsletters

11. Are there sufficient resources?

- Mechanism for collecting reports
- Database management
- Capacity to investigate
- Technical infrastructure
- Method for classifying events
- Expert analysis
- Capacity to disseminate findings and recommendations

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